69 CONGRESO NACIONAL
SOCIEDAD ESPAÑOLA DE FARMACIA HOSPITALARIA

A CORUÑA
17-19 OCT 24

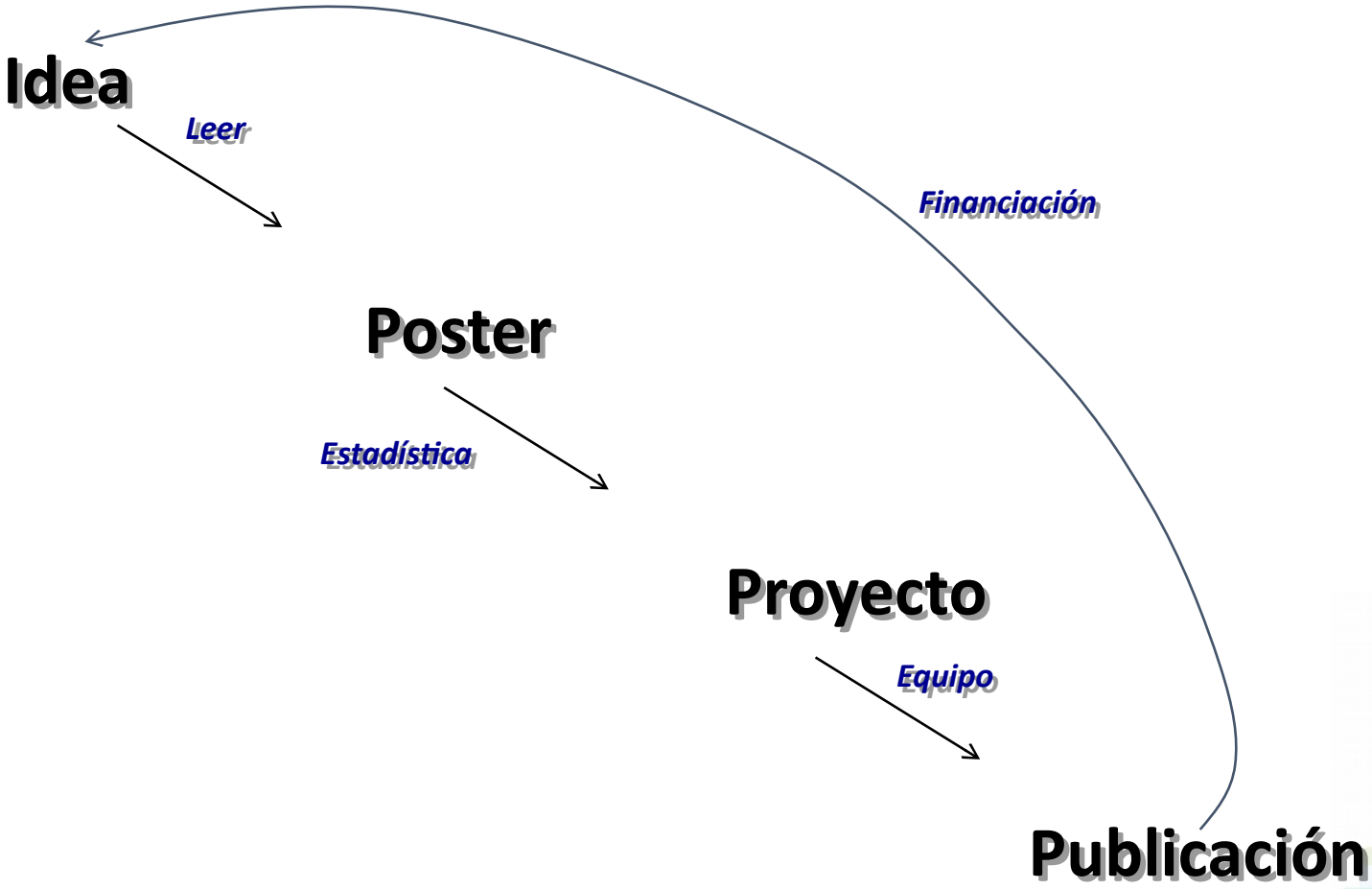
INVESTIGACIÓN CLÍNICA EN FH

@fgunico
fgunico@Gmail.com

Fernando Gutiérrez Nicolás
CHUC

sefh
Sociedad Española de Farmacia Hospitalaria

Circuito de investigación


Idea
Leer
Financiación
Poster
Estadística
Proyecto
Equipo
Publicación

08:00 - 10:30 Sala AUDITORIO ARAO

CURSO 3 - DIRECCIÓN DE INVESTIGACIÓN SEFH

CÓMO REALIZAR INVESTIGACIÓN CLÍNICA EN FARMACIA HOSPITALARIA, PRINCIPIOS BÁSICOS

Modera:

FERNANDO GUTIÉRREZ NICOLÁS
COMPLEJO HOSPITALARIO UNIVERSITARIO DE CANARIAS, SANTA CRUZ DE TENERIFE

Ponencias:

HERRAMIENTAS (DIGITALES Y ANALÓGICAS) DE AYUDA EN LA ORGANIZACIÓN DE UNA CARRERA INVESTIGADORA Y TRABAJO EN RED Y NOCIONES EN ESTADÍSTICA
FERNANDO GUTIÉRREZ NICOLÁS
COMPLEJO HOSPITALARIO UNIVERSITARIO DE CANARIAS, SANTA CRUZ DE TENERIFE

DISEÑO Y PRESENTACIÓN DE UN PROYECTO DE INVESTIGACIÓN
ANA HERNÁNDEZ GUÍO
FUNDACIÓN JIMÉNEZ DÍAZ, MADRID

CUADERNO DE RECOGIDA DE DATOS Y REDCAP
BLANCA ANAYA BAZ
RESPONSABLE DE ESTUDIOS DE INVESTIGACIÓN DE LA SEFH, CÁDIZ

REALIZACIÓN DE UN PÓSTER, CALIDAD EN EL CONTENIDO Y EL DISEÑO GRÁFICO
ANXO FERNÁNDEZ FERREIRO
HOSPITAL CLÍNICO UNIVERSITARIO DE SANTIAGO, SERGAS- IDIS

REDACCIÓN/PUBLICACIÓN DE UN ARTÍCULO CIENTÍFICO Y MANEJO DE GESTORES BIBLIOGRÁFICOS
MARTA MIARONS FONT
HOSPITAL DE VIC, BARCELONA

69 CONGRESO NACIONAL
SOCIEDAD ESPAÑOLA DE FARMACIA HOSPITALARIA

A CORUÑA
17-19 OCT 24

INVESTIGACIÓN CLÍNICA EN FH

Visión global
Estadística básica
Gestión de estudios y equipos

@fgunico
fgunico@Gmail.com

Fernando Gutiérrez Nicolás
CHUC

sefh
Sociedad Española de Farmacia Hospitalaria

¿Hay que investigar en FH?

¿Qué dicen los papeles?

20 %

Porque mejora la actividad asistencial

Te debería de dar "independencia"

Porque todos los trabajos se convierten rutinarios…

08:00 - 10:30 Sala AUDITORIO ARAO

CURSO 3 - DIRECCIÓN DE INVESTIGACIÓN SEFH

CÓMO REALIZAR INVESTIGACIÓN CLÍNICA EN FARMACIA HOSPITALARIA, PRINCIPIOS BÁSICOS

Modera:

FERNANDO GUTIÉRREZ NICOLÁS

COMPLEJO HOSPITALARIO UNIVERSITARIO DE CANARIAS, SANTA CRUZ DE TENERIFE

Ponencias:

HERRAMIENTAS (DIGITALES Y ANALÓGICAS) DE AYUDA EN LA ORGANIZACIÓN DE UNA CARRERA INVESTIGADORA Y TRABAJO EN RED Y NOCIONES EN ESTADÍSTICA

FERNANDO GUTIÉRREZ NICOLÁS

COMPLEJO HOSPITALARIO UNIVERSITARIO DE CANARIAS, SANTA CRUZ DE TENERIFE

DISEÑO Y PRESENTACIÓN DE UN PROYECTO DE INVESTIGACIÓN

ANA HERNÁNDEZ GUÍO

FUNDACIÓN JIMÉNEZ DÍAZ, MADRID

CUADERNO DE RECOGIDA DE DATOS Y REDCAP

BLANCA ANAYA BAZ

RESPONSABLE DE ESTUDIOS DE INVESTIGACIÓN DE LA SEFH, CÁDIZ

REALIZACIÓN DE UN PÓSTER, CALIDAD EN EL CONTENIDO Y EL DISEÑO GRÁFICO

ANXO FERNÁNDEZ FERREIRO

HOSPITAL CLÍNICO UNIVERSITARIO DE SANTIAGO, SERGAS- IDIS

REDACCIÓN/PUBLICACIÓN DE UN ARTÍCULO CIENTÍFICO Y MANEJO DE GESTORES BIBLIOGRÁFICOS

MARTA MIARONS FONT

HOSPITAL DE VIC, BARCELONA

¿Qué es la investigación clínica?

El sexo de los ángeles…

Aumentar supervivencia y/o reducir toxicidad

¿Para qué se investiga?

para el paciente

Finalidades de la Investigación

Experimental **Clínica**

Básica Traslacional Aplicada

Utilidad social: Mejorar la calidad de vida

¿?

The NEW ENGLAND JOURNAL of MEDICINE

Sin olvidar que el "factor de impacto" es importante…

La calidad de una institución investigadora debe valorarse por la transferencia a la parte asistencial…

¿Cómo nos organizamos nosotros?

Requisitos:

SEFH

Acepatado un poster como 1º autor en el congreso

R1

TOLEDO

Aceptado dos pósters como 1º autor en el congreso

Un minimo en el historial de 4 posters como 1º autor

R2

EUROPEO

Aceptado dos pósters como 1º autor en el congreso

Un minimo en el historial de 6 posters como 1º autor

Enviado 1 artículo* a una revista (con o sin IP)

R3

SEIMC

Aceptado un pósters como 1º autor en el congreso

Un minimo en el historial de 8 posters como 1º autor

Enviado dos artículos* a una revista (con o sin IP) o aceptado un artículo* (con o sin IP)

SEFH (2ª vez)

Aceptado dos pósters como 1º autor en el congreso

Un minimo en el historial de 15 posters como 1º autor

Un mínimo de un artículo* aceptado (con o sin F)

Enviado un "artículo" a una revista con IP

Proyecto de investigación evaluado y aceptado por el CEIC

R4

Dificultad

*Artículo: original o caso clínico

08:00 - 10:30 Sala AUDITORIO ARAO

CURSO 3 - DIRECCIÓN DE INVESTIGACIÓN SEFH

CÓMO REALIZAR INVESTIGACIÓN CLÍNICA EN FARMACIA HOSPITALARIA, PRINCIPIOS BÁSICOS

Modera:

FERNANDO GUTIÉRREZ NICOLÁS
COMPLEJO HOSPITALARIO UNIVERSITARIO DE CANARIAS, SANTA CRUZ DE TENERIFE

Ponencias:

HERRAMIENTAS (DIGITALES Y ANALÓGICAS) DE AYUDA EN LA ORGANIZACIÓN DE UNA CARRERA INVESTIGADORA Y TRABAJO EN RED Y NOCIONES EN ESTADÍSTICA
FERNANDO GUTIÉRREZ NICOLÁS
COMPLEJO HOSPITALARIO UNIVERSITARIO DE CANARIAS, SANTA CRUZ DE TENERIFE

DISEÑO Y PRESENTACIÓN DE UN PROYECTO DE INVESTIGACIÓN
ANA HERNÁNDEZ GUÍO
FUNDACIÓN JIMÉNEZ DÍAZ, MADRID

CUADERNO DE RECOGIDA DE DATOS Y REDCAP
BLANCA ANAYA BAZ
RESPONSABLE DE ESTUDIOS DE INVESTIGACIÓN DE LA SEFH, CÁDIZ

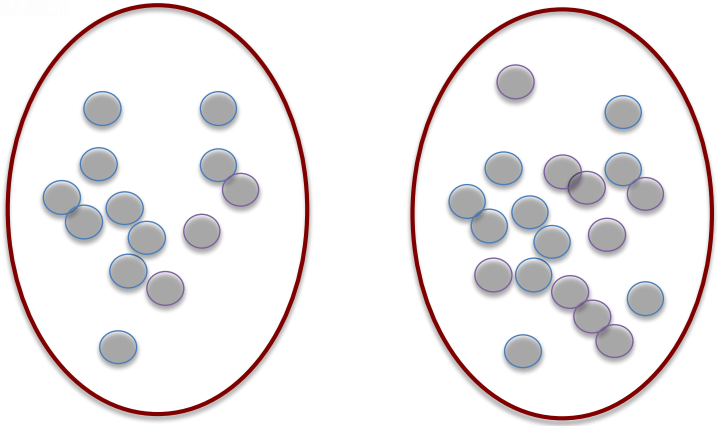
REALIZACIÓN DE UN PÓSTER, CALIDAD EN EL CONTENIDO Y EL DISEÑO GRÁFICO
ANXO FERNÁNDEZ FERREIRO
HOSPITAL CLÍNICO UNIVERSITARIO DE SANTIAGO, SERGAS- IDIS

REDACCIÓN/PUBLICACIÓN DE UN ARTÍCULO CIENTÍFICO Y MANEJO DE GESTORES BIBLIOGRÁFICOS
MARTA MIARONS FONT
HOSPITAL DE VIC, BARCELONA

Estadística Básica

96%

¿Qué es la estadística?

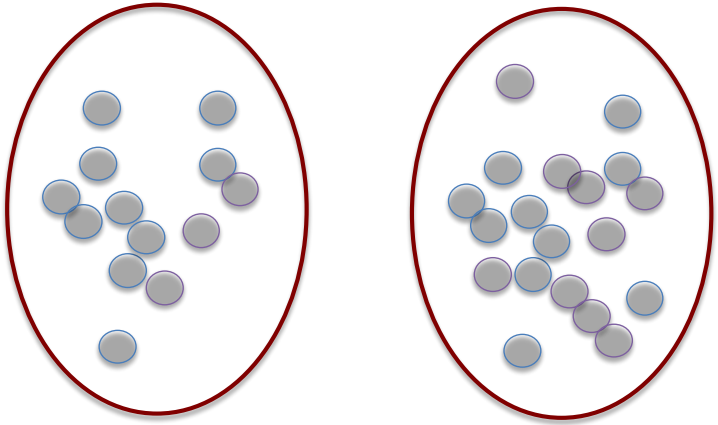


En la sencillez está la brillantez

¿Hay diferencias?

Y como todo, tiene unas reglas…

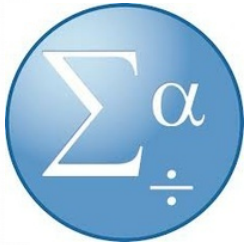
¿Hay diferencias?

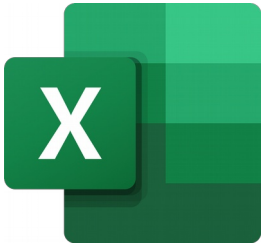


$p < 0,05$

Ya sabemos si hay diferencia o no

Vamos a ver si sabemos hacerlo





Reales	Adherente	No adherente	
1 comp	16	2	18
> 1 comp	3	7	10
	19	9	28

Esperados	Adherente	No adherente	
1 comp	12,2142857	5,785714286	18
> 1 comp	6,78571429	3,214285714	10
	19	9	28

IC 95%	2,53243822
	137,592476
OR=	18,6666667
p=	0,00138837

Adherente No adherente

Ejemplo

The NEW ENGLAND JOURNAL of MEDI

ORIGINAL ARTICLE

Alectinib versus Crizotinib in *ALK*-Positive Non–Small-Cell L

BACKGROUND

Alectinib, a highly selective inhibitor of anaplastic lymphoma kinase (ALK), has shown systemic and central nervous system (CNS) efficacy in the treatment of *ALK*-positive non–small-cell lung cancer (NSCLC). We investigated alectinib as compared with crizotinib in patients with previously untreated, advanced *ALK*-positive NSCLC, including those with asymptomatic CNS disease.

METHODS

In a randomized, open-label, phase 3 trial, we randomly assigned 303 patients with previously untreated, advanced *ALK*-positive NSCLC to receive either alectinib (600 mg twice daily) or crizotinib (250 mg twice daily). The primary end point was investigator-assessed progression-free survival. Secondary end points were independent review committee–assessed progression-free survival, time to CNS progression, objective response rate, and overall survival.

RESULTS

During a median follow-up of 17.6 months (crizotinib) and 18.6 months (alectinib), an event of disease progression or death occurred in 62 of 152 patients (41%) in the alectinib group and 102 of 151 patients (68%) in the crizotinib group. The rate of investigator-assessed progression-free survival was significantly higher with alectinib than with crizotinib (12-month event-free survival rate, 68.4% [95% confidence interval (CI), 61.0 to 75.9] with alectinib vs. 48.7% [95% CI, 40.4 to 56.9] with crizotinib; hazard ratio for disease progression or death, 0.47 [95% CI, 0.34 to 0.65]; P<0.001); the median progression-free survival with alectinib was not reached. The results for independent review committee–assessed progression-free survival were consistent with those for the primary end point. A total of 18 patients (12%) in the alectinib group had an event of CNS progression, as compared with 68 patients (45%) in the crizotinib group (cause-specific hazard ratio, 0.16; 95% CI, 0.10 to 0.28; P<0.001). A response occurred in 126 patients in the alectinib group (response rate, 82.9%; 95% CI, 76.0 to 88.5) and in 114 patients in the crizotinib group (response rate, 75.5%; 95% CI, 67.8 to 82.1) (P=0.09). Grade 3 to 5 adverse events were less frequent with alectinib (41% vs. 50% with crizotinib).

CONCLUSIONS

As compared with crizotinib, alectinib showed superior efficacy and lower toxicity in primary treatment of *ALK*-positive NSCLC. (Funded by F. Hoffmann–La Roche; ALEX ClinicalTrials.gov number, NCT02075840.)

BACKGROUND

Alectinib, a highly selective inhibitor of anaplastic lymphoma kinase (ALK), has shown systemic and central nervous system (CNS) efficacy in the treatment of *ALK*-positive non–small-cell lung cancer (NSCLC). We investigated alectinib as compared with crizotinib in patients with previously untreated, advanced *ALK*-positive NSCLC, including those with asymptomatic CNS disease.

METHODS

In a randomized, open-label, phase 3 trial, we randomly assigned 303 patients with previously untreated, advanced *ALK*-positive NSCLC to receive either alectinib (600 mg twice daily) or crizotinib (250 mg twice daily). The primary end point was investigator-assessed progression-free survival. Secondary end points were independent review committee–assessed progression-free survival, time to CNS progression, objective response rate, and overall survival.

¿Hay diferencias?

RESULTS

During a median follow-up of 17.6 months (crizotinib) and 18.6 months (alectinib), an event of disease progression or death occurred in 62 of 152 patients (41%) in the alectinib group and 102 of 151 patients (68%) in the crizotinib group. The rate of investigator-assessed progression-free survival was significantly higher with alectinib than with crizotinib (12-month event-free survival rate, 68.4% [95% confidence interval (CI), 61.0 to 75.9] with alectinib vs. 48.7% [95% CI, 40.4 to 56.9] with crizotinib; hazard ratio for disease progression or death, 0.47 [95% CI, 0.34 to 0.65]; P<0.001); the median progression-free survival with alectinib was not reached. The results for independent review committee–assessed progression-free survival were consistent with those for the primary end point. A total of 18 patients (12%) in the alectinib group had an event of CNS progression, as compared with 68 patients (45%) in the crizotinib group (cause-specific hazard ratio, 0.16; 95% CI, 0.10 to 0.28; P<0.001). A response occurred in 126 patients in the alectinib group (response rate, 82.9%; 95% CI, 76.0 to 88.5) and in 114 patients in the crizotinib group (response rate, 75.5%; 95% CI, 67.8 to 82.1) (P=0.09). Grade 3 to 5 adverse events were less frequent with alectinib (41% vs. 50% with crizotinib).

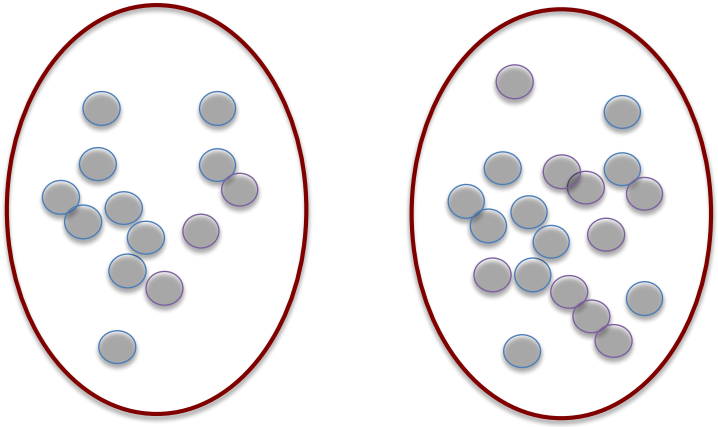
Por tanto:

En 12 meses, han progresado más pacientes con crizotinib que con alectinib,

¿Hay diferencias?

RESULTS

During a median follow-up of 17.6 months (crizotinib) and 18.6 months (alectinib), an event of disease progression or death occurred in 62 of 152 patients (41%) in the alectinib group and 102 of 151 patients (68%) in the crizotinib group. The rate of investigator-assessed progression-free survival was significantly higher with alectinib than with crizotinib (12-month event-free survival rate, 68.4% [95% confidence interval (CI), 61.0 to 75.9] with alectinib vs. 48.7% [95% CI, 40.4 to 56.9] with crizotinib; hazard ratio for disease progression or death, 0.47 [95% CI, 0.34 to 0.65]; P<0.001); the median progression-free survival with alectinib was not reached. The results for independent review committee–assessed progression-free survival were consistent with those for the primary end point. A total of 18 patients (12%) in the alectinib group had an event of CNS progression, as compared with 68 patients (45%) in the crizotinib group (cause-specific hazard ratio, 0.16; 95% CI, 0.10 to 0.28; P<0.001). A response occurred in 126 patients in the alectinib group (response rate, 82.9%; 95% CI, 76.0 to 88.5) and in 114 patients in the crizotinib group (response rate, 75.5%; 95% CI, 67.8 to 82.1) (P=0.09). Grade 3 to 5 adverse events were less frequent with alectinib (41% vs. 50% with crizotinib).



Han progresado:

48,7% ***68,4%***

¿Hay diferencias?

$p < 0,05$

¿Hay diferencias?

RESULTS

During a median follow-up of 17.6 months (crizotinib) and 18.6 months (alectinib), an event of disease progression or death occurred in 62 of 152 patients (41%) in the alectinib group and 102 of 151 patients (68%) in the crizotinib group. The rate of investigator-assessed progression-free survival was significantly higher with alectinib than with crizotinib (12-month event-free survival rate, 68.4% [95% confidence interval (CI), 61.0 to 75.9] with alectinib vs. 48.7% [95% CI, 40.4 to 56.9] with crizotinib; hazard ratio for disease progression or death, 0.47 [95% CI, 0.34 to 0.65]; P<0.001); the median progression-free survival with alectinib was not reached. The results for independent review committee–assessed progression-free survival were consistent with those for the primary end point. A total of 18 patients (12%) in the alectinib group had an event of CNS progression, as compared with 68 patients (45%) in the crizotinib group (cause-specific hazard ratio, 0.16; 95% CI, 0.10 to 0.28; P<0.001). A response occurred in 126 patients in the alectinib group (response rate, 82.9%; 95% CI, 76.0 to 88.5) and in 114 patients in the crizotinib group (response rate, 75.5%; 95% CI, 67.8 to 82.1) (P=0.09). Grade 3 to 5 adverse events were less frequent with alectinib (41% vs. 50% with crizotinib).

Por tanto:

En 12 meses, han progresado más pacientes con crizotinib, y como la "p" es menor a 0,05:

Con alectinib los pacientes tienen un PFS superior, es decir, la enfermedad avanza más lenta…

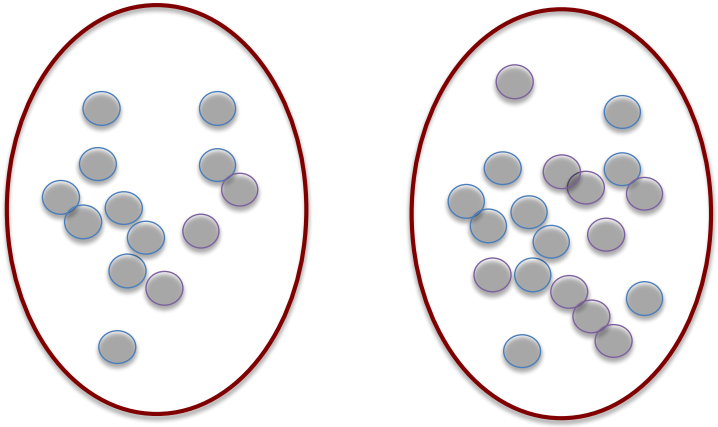
Con crizotinib los pacientes tienen un PFS inferior, es decir, la enfermedad avanza más rápido…

¿Qué más podemos sacar del resumen?

¿Hay diferencias?

RESULTS

During a median follow-up of 17.6 months (crizotinib) and 18.6 months (alectinib), an event of disease progression or death occurred in 62 of 152 patients (41%) in the alectinib group and 102 of 151 patients (68%) in the crizotinib group. The rate of investigator-assessed progression-free survival was significantly higher with alectinib than with crizotinib (12-month event-free survival rate, 68.4% [95% confidence interval (CI), 61.0 to 75.9] with alectinib vs. 48.7% [95% CI, 40.4 to 56.9] with crizotinib; hazard ratio for disease progression or death, 0.47 [95% CI, 0.34 to 0.65]; P<0.001); the median progression-free survival with alectinib was not reached. The results for independent review committee–assessed progression-free survival were consistent with those for the primary end point. A total of 18 patients (12%) in the alectinib group had an event of CNS progression, as compared with 68 patients (45%) in the crizotinib group (cause-specific hazard ratio, 0.16; 95% CI, 0.10 to 0.28; P<0.001). A response occurred in 126 patients in the alectinib group (response rate, 82.9%; 95% CI, 76.0 to 88.5) and in 114 patients in the crizotinib group (response rate, 75.5%; 95% CI, 67.8 to 82.1) (P=0.09). Grade 3 to 5 adverse events were less frequent with alectinib (41% vs. 50% with crizotinib).



Han progresado:

12 % ***45 %***

¿Hay diferencias?

$p < 0.05$

¿Hay diferencias?

RESULTS

During a median follow-up of 17.6 months (crizotinib) and 18.6 months (alectinib), an event of disease progression or death occurred in 62 of 152 patients (41%) in the alectinib group and 102 of 151 patients (68%) in the crizotinib group. The rate of investigator-assessed progression-free survival was significantly higher with alectinib than with crizotinib (12-month event-free survival rate, 68.4% [95% confidence interval (CI), 61.0 to 75.9] with alectinib vs. 48.7% [95% CI, 40.4 to 56.9] with crizotinib; hazard ratio for disease progression or death, 0.47 [95% CI, 0.34 to 0.65]; P<0.001); the median progression-free survival with alectinib was not reached. The results for independent review committee–assessed progression-free survival were consistent with those for the primary end point. A total of 18 patients (12%) in the alectinib group had an event of CNS progression, as compared with 68 patients (45%) in the crizotinib group (cause-specific hazard ratio, 0.16; 95% CI, 0.10 to 0.28; P<0.001). A response occurred in 126 patients in the alectinib group (response rate, 82.9%; 95% CI, 76.0 to 88.5) and in 114 patients in the crizotinib group (response rate, 75.5%; 95% CI, 67.8 to 82.1) (P=0.09). Grade 3 to 5 adverse events were less frequent with alectinib (41% vs. 50% with crizotinib).

Por tanto:

En 12 meses, han progresado más pacientes con crizotinib, y como la "p" es menor a 0,05:

Con alectinib los pacientes tienen un PFS superior, es decir, la enfermedad avanza más lenta…

Con crizotinib los pacientes tienen un PFS inferior, es decir, la enfermedad avanza más rápido…

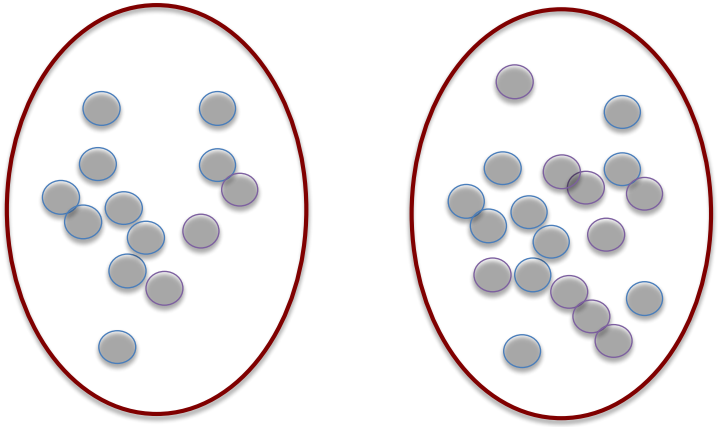
También limita la aparición de lesiones en el SNC

¿Qué más podemos sacar del resumen?

¿Hay diferencias?

RESULTS

During a median follow-up of 17.6 months (crizotinib) and 18.6 months (alectinib), an event of disease progression or death occurred in 62 of 152 patients (41%) in the alectinib group and 102 of 151 patients (68%) in the crizotinib group. The rate of investigator-assessed progression-free survival was significantly higher with alectinib than with crizotinib (12-month event-free survival rate, 68.4% [95% confidence interval (CI), 61.0 to 75.9] with alectinib vs. 48.7% [95% CI, 40.4 to 56.9] with crizotinib; hazard ratio for disease progression or death, 0.47 [95% CI, 0.34 to 0.65]; P<0.001); the median progression-free survival with alectinib was not reached. The results for independent review committee–assessed progression-free survival were consistent with those for the primary end point. A total of 18 patients (12%) in the alectinib group had an event of CNS progression, as compared with 68 patients (45%) in the crizotinib group (cause-specific hazard ratio, 0.16; 95% CI, 0.10 to 0.28; P<0.001). A response occurred in 126 patients in the alectinib group (response rate, 82.9%; 95% CI, 76.0 to 88.5) and in 114 patients in the crizotinib group (response rate, 75.5%; 95% CI, 67.8 to 82.1) (P=0.09). Grade 3 to 5 adverse events were less frequent with alectinib (41% vs. 50% with crizotinib).



Han progresado:

82,9 % ***75,5 %***

¿Hay diferencias?

$p < 0,05$

¿Hay diferencias?

RESULTS

During a median follow-up of 17.6 months (crizotinib) and 18.6 months (alectinib), an event of disease progression or death occurred in 62 of 152 patients (41%) in the alectinib group and 102 of 151 patients (68%) in the crizotinib group. The rate of investigator-assessed progression-free survival was significantly higher with alectinib than with crizotinib (12-month event-free survival rate, 68.4% [95% confidence interval (CI), 61.0 to 75.9] with alectinib vs. 48.7% [95% CI, 40.4 to 56.9] with crizotinib; hazard ratio for disease progression or death, 0.47 [95% CI, 0.34 to 0.65]; P<0.001); the median progression-free survival with alectinib was not reached. The results for independent review committee–assessed progression-free survival were consistent with those for the primary end point. A total of 18 patients (12%) in the alectinib group had an event of CNS progression, as compared with 68 patients (45%) in the crizotinib group (cause-specific hazard ratio, 0.16; 95% CI, 0.10 to 0.28; P<0.001). A response occurred in 126 patients in the alectinib group (response rate, 82.9%; 95% CI, 76.0 to 88.5) and in 114 patients in the crizotinib group (response rate, 75.5%; 95% CI, 67.8 to 82.1) (P=0.09). Grade 3 to 5 adverse events were less frequent with alectinib (41% vs. 50% with crizotinib).

Por tanto:

En 12 meses, han progresado más pacientes con crizotinib, y como la "p" es menor a 0,05:

Con alectinib los pacientes tienen un PFS superior, es decir, la enfermedad avanza más lenta…

Con crizotinib los pacientes tienen un PFS inferior, es decir, la enfermedad avanza más rápido…

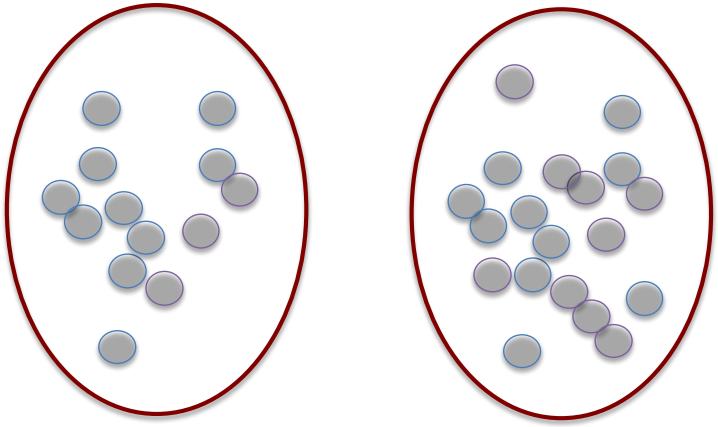
También limita la aparición de lesiones en el SNC

NO tiene mejores tasas de respuesta

¿Hay diferencias?

RESULTS

During a median follow-up of 17.6 months (crizotinib) and 18.6 months (alectinib), an event of disease progression or death occurred in 62 of 152 patients (41%) in the alectinib group and 102 of 151 patients (68%) in the crizotinib group. The rate of investigator-assessed progression-free survival was significantly higher with alectinib than with crizotinib (12-month event-free survival rate, 68.4% [95% confidence interval (CI), 61.0 to 75.9] with alectinib vs. 48.7% [95% CI, 40.4 to 56.9] with crizotinib; hazard ratio for disease progression or death, 0.47 [95% CI, 0.34 to 0.65]; P<0.001); the median progression-free survival with alectinib was not reached. The results for independent review committee–assessed progression-free survival were consistent with those for the primary end point. A total of 18 patients (12%) in the alectinib group had an event of CNS progression, as compared with 68 patients (45%) in the crizotinib group (cause-specific hazard ratio, 0.16; 95% CI, 0.10 to 0.28; P<0.001). A response occurred in 126 patients in the alectinib group (response rate, 82.9%; 95% CI, 76.0 to 88.5) and in 114 patients in the crizotinib group (response rate, 75.5%; 95% CI, 67.8 to 82.1) (P=0.09). Grade 3 to 5 adverse events were less frequent with alectinib (41% vs. 50% with crizotinib).



Han progresado:

41 % ***52 %***

¿Hay diferencias?

$p < 0.05$

¿Hay diferencias?

RESULTS

During a median follow-up of 17.6 months (crizotinib) and 18.6 months (alectinib), an event of disease progression or death occurred in 62 of 152 patients (41%) in the alectinib group and 102 of 151 patients (68%) in the crizotinib group. The rate of investigator-assessed progression-free survival was significantly higher with alectinib than with crizotinib (12-month event-free survival rate, 68.4% [95% confidence interval (CI), 61.0 to 75.9] with alectinib vs. 48.7% [95% CI, 40.4 to 56.9] with crizotinib; hazard ratio for disease progression or death, 0.47 [95% CI, 0.34 to 0.65]; P<0.001); the median progression-free survival with alectinib was not reached. The results for independent review committee–assessed progression-free survival were consistent with those for the primary end point. A total of 18 patients (12%) in the alectinib group had an event of CNS progression, as compared with 68 patients (45%) in the crizotinib group (cause-specific hazard ratio, 0.16; 95% CI, 0.10 to 0.28; P<0.001). A response occurred in 126 patients in the alectinib group (response rate, 82.9%; 95% CI, 76.0 to 88.5) and in 114 patients in the crizotinib group (response rate, 75.5%; 95% CI, 67.8 to 82.1) (P=0.09). Grade 3 to 5 adverse events were less frequent with alectinib (41% vs. 50% with crizotinib).

¿¿??

Por tanto:

En 12 meses, han progresado más pacientes con crizotinib, y como la "p" es menor a 0,05:

Con alectinib los pacientes tienen un PFS superior, es decir, la enfermedad avanza más lenta…

Con crizotinib los pacientes tienen un PFS inferior, es decir, la enfermedad avanza más rápido…

También limita la aparición de lesiones en el SNC

No tiene mejores tasas de respuesta

No tiene diferencias en toxicidad


¿Cómo vamos?

Otro ejemplo…

ORIGINAL ARTICLE

Olaparib for Metastatic Breast Cancer in Patients with a Germline *BRCA* Mutation

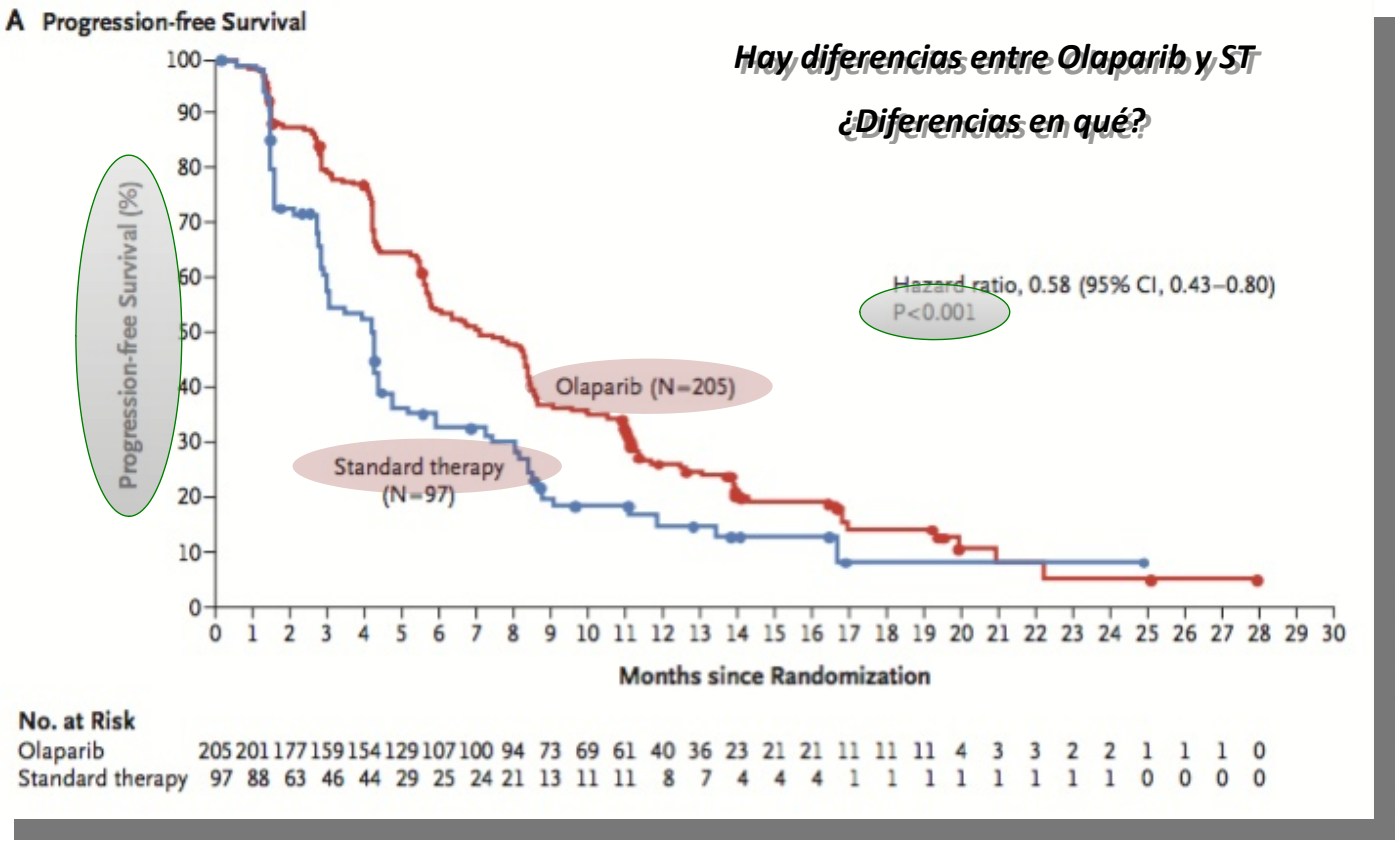
Mark Robson, M.D., Seock-Ah Im, M.D., Ph.D., Elżbieta Senkus, M.D., Ph.D.,

METHODS

We conducted a randomized, open-label, phase 3 trial in which olaparib monotherapy was compared with standard therapy in patients with a germline *BRCA* mutation and human epidermal growth factor receptor type 2 (HER2)–negative metastatic breast cancer who had received no more than two previous chemotherapy regimens for metastatic disease. Patients were randomly assigned, in a 2:1 ratio, to receive olaparib tablets (300 mg twice daily) or standard therapy with single-agent chemotherapy of the physician's choice (capecitabine, eribulin, or vinorelbine in 21-day cycles). The primary end point was progression-free survival, which was assessed by blinded independent central review and was analyzed on an intention-to-treat basis.

RESULTS

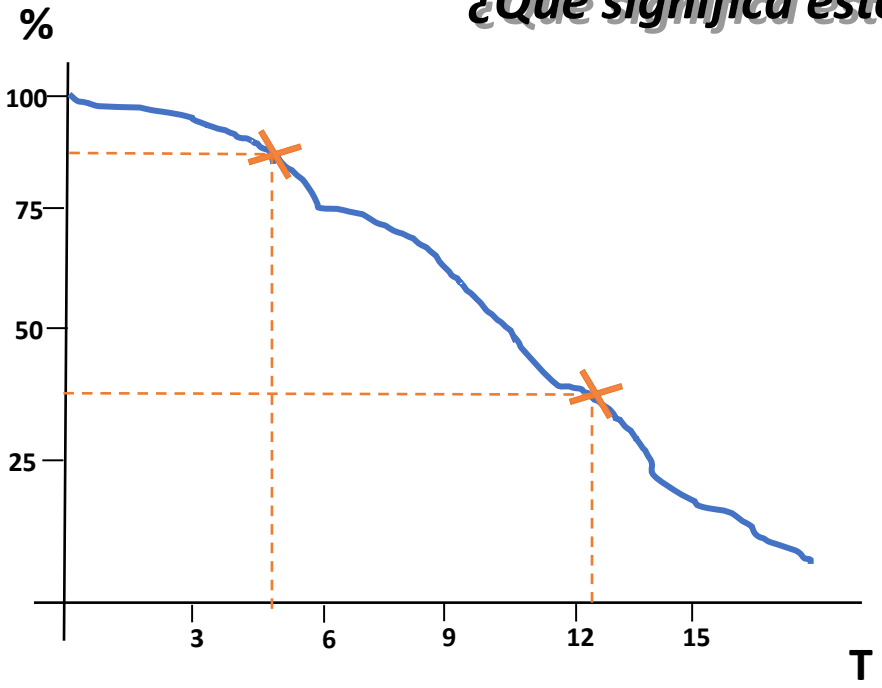
Of the 302 patients who underwent randomization, 205 were assigned to receive olaparib and 97 were assigned to receive standard therapy. Median progression-free survival was significantly longer in the olaparib group than in the standard-therapy group (7.0 months vs. 4.2 months; hazard ratio for disease progression or death, 0.58; 95% confidence interval, 0.43 to 0.80; P<0.001). The response rate was 59.9% in the olaparib group and 28.8% in the standard-therapy group. The rate of grade 3 or higher adverse events was 36.6% in the olaparib group and 50.5% in the standard-therapy group, and the rate of treatment discontinuation due to toxic effects was 4.9% and 7.7%, respectively.

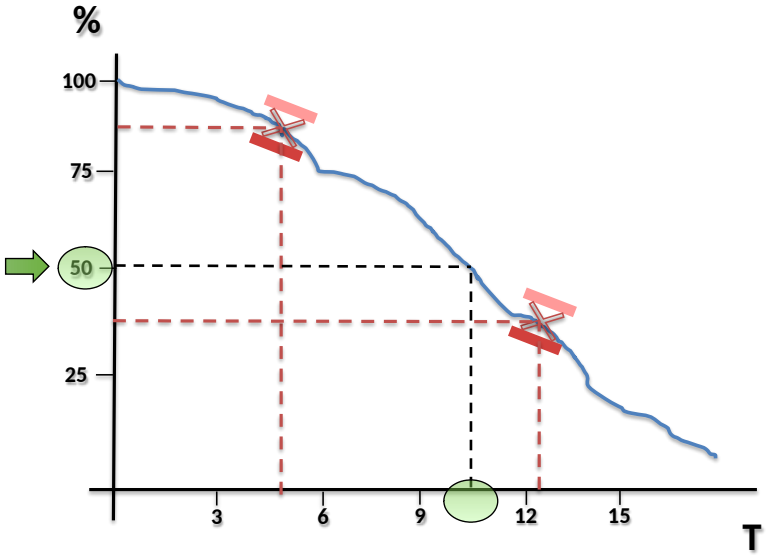


Hay diferencias entre Olaparib y ST

¿Diferencias en qué?

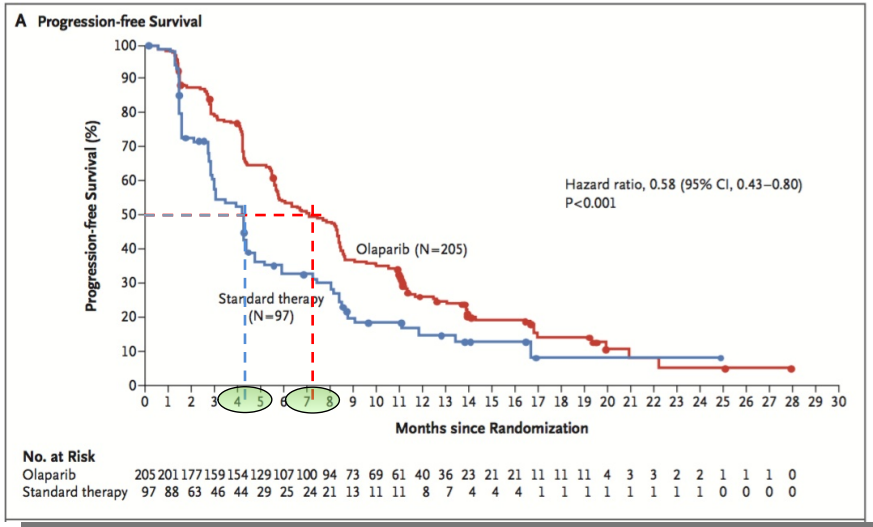
¿Qué significa esto?





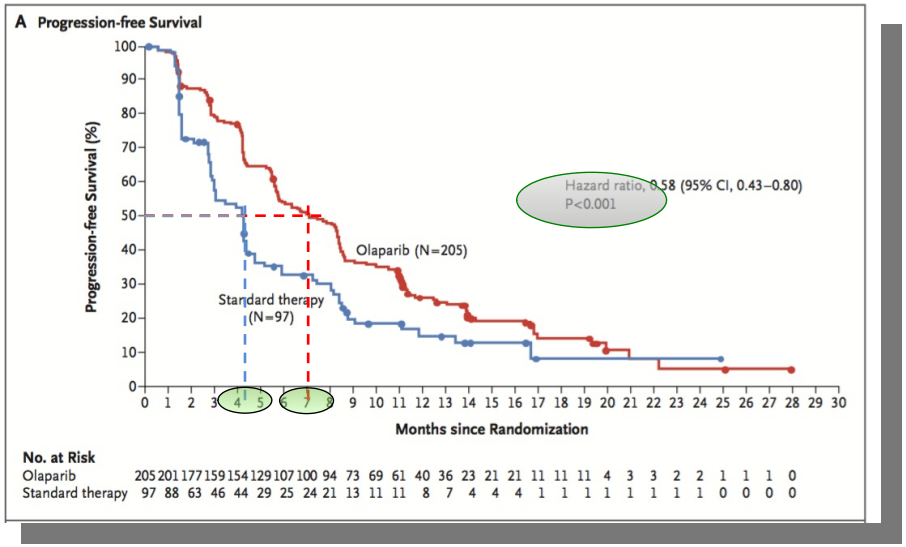
RESULTS

Of the 302 patients who underwent randomization, 205 were assigned to receive olaparib and 97 were assigned to receive standard therapy. Median progression-free survival was significantly longer in the olaparib group than in the standard-therapy group (7.0 months vs. 4.2 months; hazard ratio for disease progression or death, 0.58; 95% confidence interval, 0.43 to 0.80; P<0.001). The response rate was 59.9% in the olaparib group and 28.8% in the standard-therapy group. The rate of grade 3 or higher adverse events was 36.6% in the olaparib group and 50.5% in the standard-therapy group, and the rate of treatment discontinuation due to toxic effects was 4.9% and 7.7%, respectively.



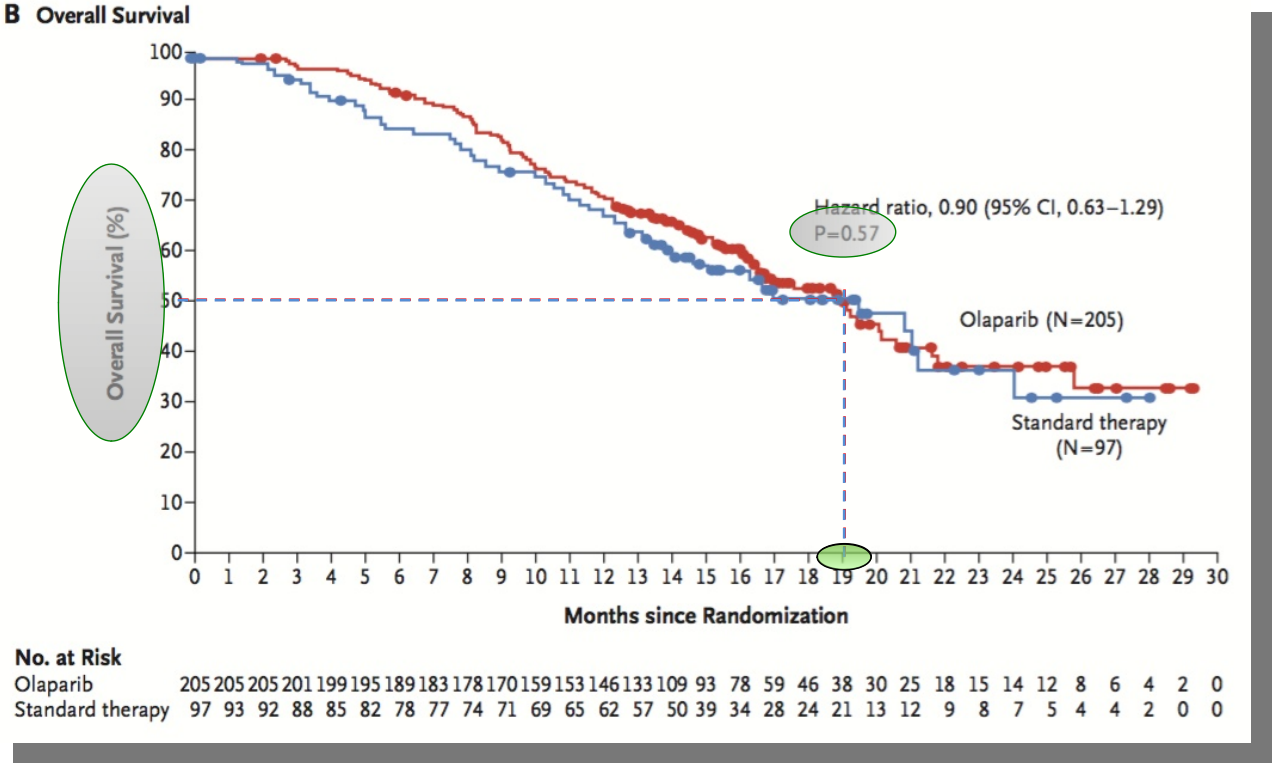
RESULTS

Of the 302 patients who underwent randomization, 205 were assigned to receive olaparib and 97 were assigned to receive standard therapy. Median progression-free survival was significantly longer in the olaparib group than in the standard-therapy group (7.0 months vs. 4.2 months; hazard ratio for disease progression or death, 0.58; 95% confidence interval, 0.43 to 0.80; P<0.001). The response rate was 59.9% in the olaparib group and 28.8% in the standard-therapy group. The rate of grade 3 or higher adverse events was 36.6% in the olaparib group and 50.5% in the standard-therapy group, and the rate of treatment discontinuation due to toxic effects was 4.9% and 7.7%, respectively.



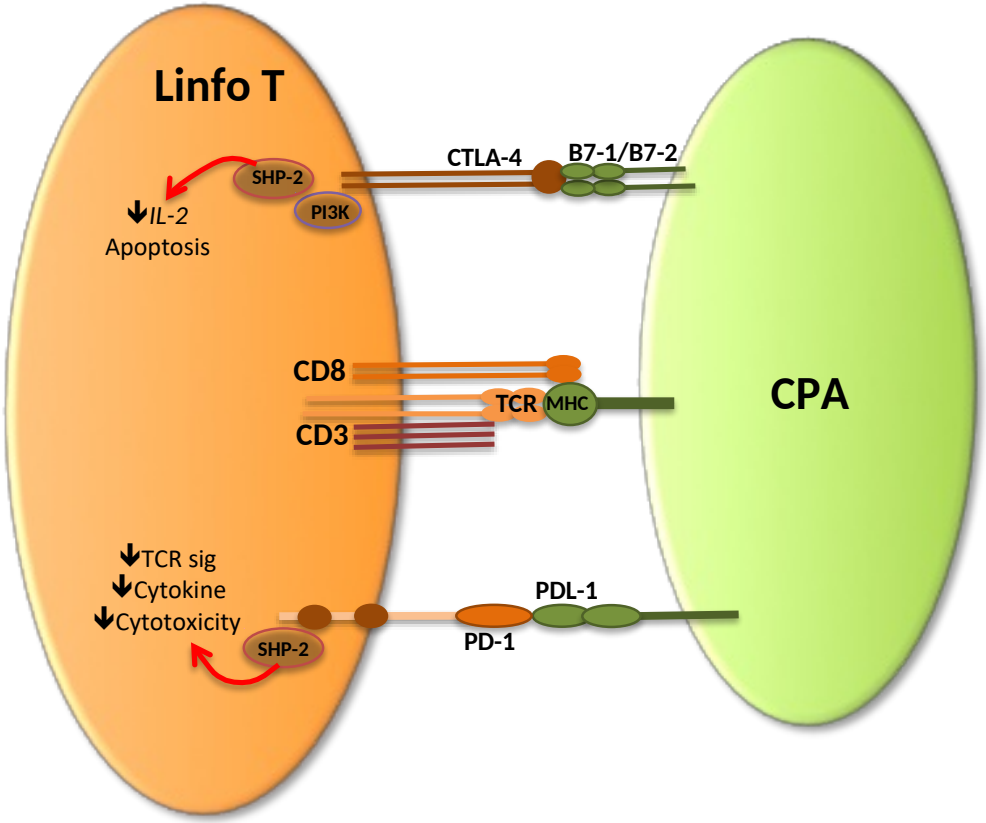
¿Cuál es mejor?

¿Cuál es mejor?



Lógico!! Tiene el mismo valor de mediana de OS

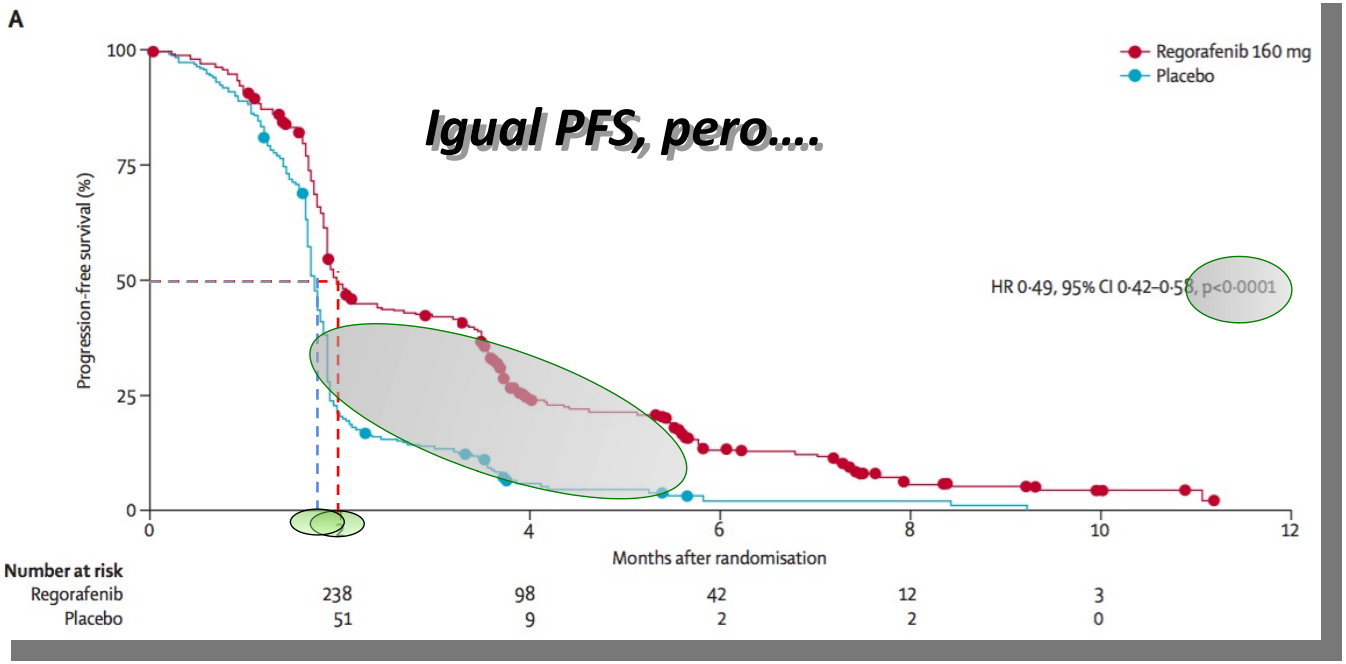
Un ejemplo diferente y que pasa mucho en inmunoterapia


Linfo T
SHP-2
PI3K
↓IL-2
Apoptosis
CTLA-4
B7-1/B7-2
CD8
TCR
MHC
CD3
CPA
↓TCR sig
↓Cytokine
↓Cytotoxicity
SHP-2
PDL-1
PD-1

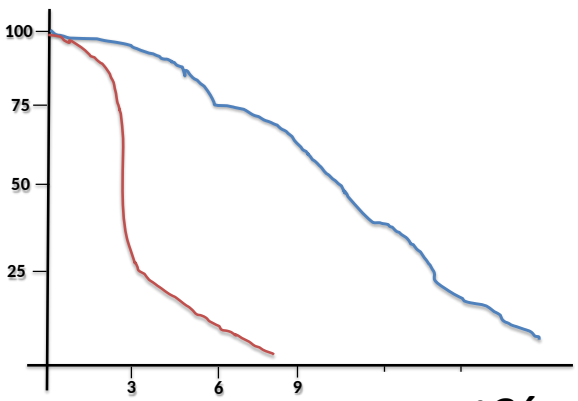
El valor de mediana NO sirve de nada!!!

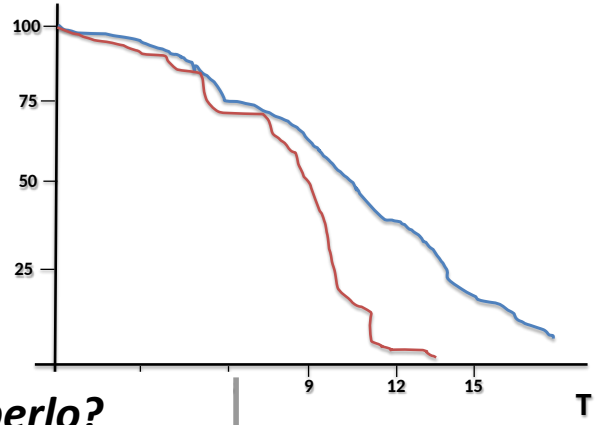
Regorafenib monotherapy for previously treated metastatic colorectal cancer (CORRECT): an international, multicentre, randomised, placebo-controlled, phase 3 trial

Axel Grothey*, Eric Van Cutsem*, Alberto Sobrero, Salvatore Siena, Alfredo Falcone, Marc Ychou, Yves Humblet, Olivier Bouché, Laurent Mineur,

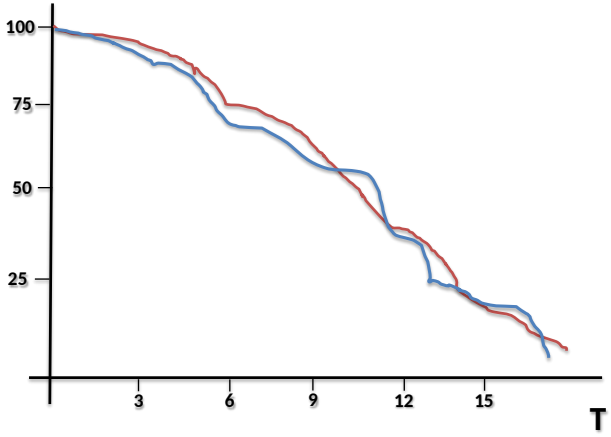


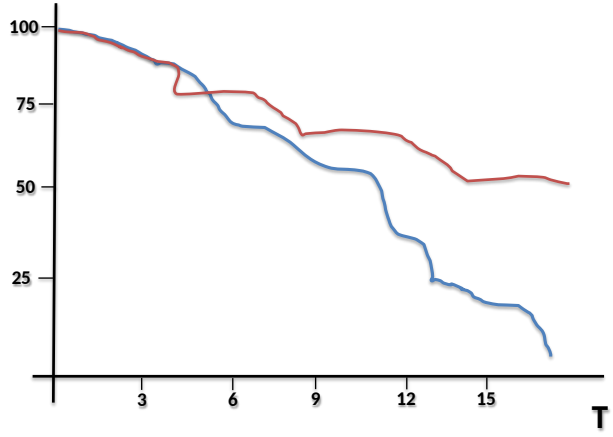
La separación de las curvas…





¿Cómo saberlo?





ORIGINAL ARTICLE

Olaparib for Metastatic Breast Cancer in Patients with a Germline *BRCA* Mutation

Mark Robson, M.D., Seock-Ah Im, M.D., Ph.D., Elżbieta Senkus, M.D., Ph.D.,

METHODS

We conducted a randomized, open-label, phase 3 trial in which olaparib monotherapy was compared with standard therapy in patients with a germline *BRCA* mutation and human epidermal growth factor receptor type 2 (HER2)–negative metastatic breast cancer who had received no more than two previous chemotherapy regimens for metastatic disease. Patients were randomly assigned, in a 2:1 ratio, to receive olaparib tablets (300 mg twice daily) or standard therapy with single-agent chemotherapy of the physician's choice (capecitabine, eribulin, or vinorelbine in 21-day cycles). The primary end point was progression-free survival, which was assessed by blinded independent central review and was analyzed on an intention-to-treat basis.

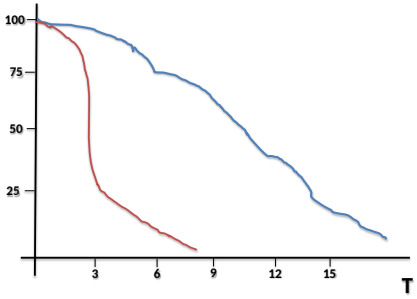
RESULTS

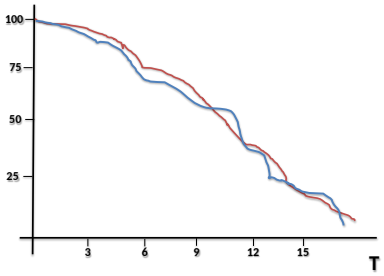
Of the 302 patients who underwent randomization, 205 were assigned to receive olaparib and 97 were assigned to receive standard therapy. Median progression-free survival was significantly longer in the olaparib group than in the standard-therapy group (7.0 months vs. 4.2 months; hazard ratio for disease progression or death, 0.58; 95% confidence interval, 0.43 to 0.80; P<0.001). The response rate was 59.9% in the olaparib group and 28.8% in the standard-therapy group. The rate of grade 3 or higher adverse events was 36.6% in the olaparib group and 50.5% in the standard-therapy group, and the rate of treatment discontinuation due to toxic effects was 4.9% and 7.7%, respectively.

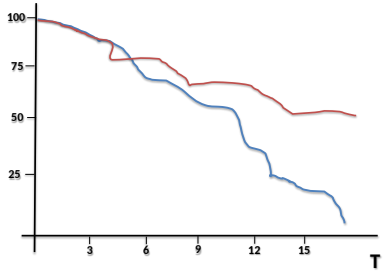
¿Qué es el HR?

Es una valor RELATIVO = $\frac{\text{Calidad de A}}{\text{Calidad de B}}$

¿Si B es mejor que A?	*¿Si B = A?*	*¿Si A es mejor que B?*
HR < 1	**HR = 1**	**HR > 1**







HR = 1

Subgroup	Olaparib	Standard Therapy	Hazard Ratio (95% CI)
	no. of patients with events/total no. (%)		
All patients	163/205 (79.5)	71/97 (73.2)	0.58 (0.43–0.80)
Previous chemotherapy for metastatic breast cancer			
Yes	119/146 (81.5)	51/69 (73.9)	0.65 (0.47–0.91)
No	44/59 (74.6)	20/28 (71.4)	0.56 (0.34–0.98)
Hormone-receptor status			
Hormone-receptor positive	82/103 (79.6)	31/49 (63.3)	0.82 (0.55–1.26)
Triple negative	81/102 (79.4)	40/48 (83.3)	0.43 (0.29–0.63)
Previous platinum-based therapy for breast cancer			
Yes	50/60 (83.3)	21/26 (80.8)	0.67 (0.41–1.14)
No	113/145 (77.9)	50/71 (70.4)	0.60 (0.43–0.84)
Measurable disease			
Yes	139/165 (84.2)	56/72 (77.8)	0.58 (0.43–0.80)
No	24/40 (60.0)	15/25 (60.0)	0.57 (0.30–1.12)
Progressive disease at the time of randomization			
Yes	127/159 (79.9)	53/73 (72.6)	0.60 (0.43–0.83)
No	36/46 (78.3)	18/24 (75.0)	0.72 (0.41–1.30)
BRCA mutation type			
BRCA1	94/114 (82.5)	41/50 (82.0)	0.54 (0.37–0.79)
BRCA2	64/84 (76.2)	30/45 (66.7)	0.68 (0.45–1.07)
Age			
<65 yr	154/194 (79.4)	67/93 (72.0)	0.66 (0.49–0.88)
≥65 yr	9/11 (81.8)	4/4 (100.0)	Not calculated
Region			
Asia	46/59 (78.0)	21/28 (75.0)	0.57 (0.34–0.97)
Europe	77/97 (79.4)	34/35 (75.6)	0.71 (0.48–1.08)
North America and South America	40/49 (81.6)	16/24 (66.7)	0.39 (0.22–0.73)
Race			
White	109/134 (81.3)	47/63 (74.6)	0.67 (0.48–0.95)
Other	54/71 (76.1)	24/34 (70.6)	0.51 (0.32–0.85)

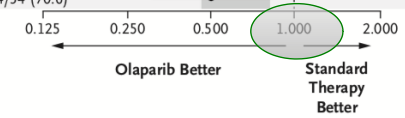
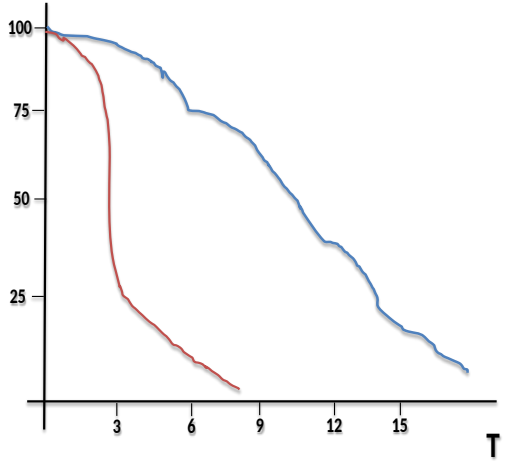
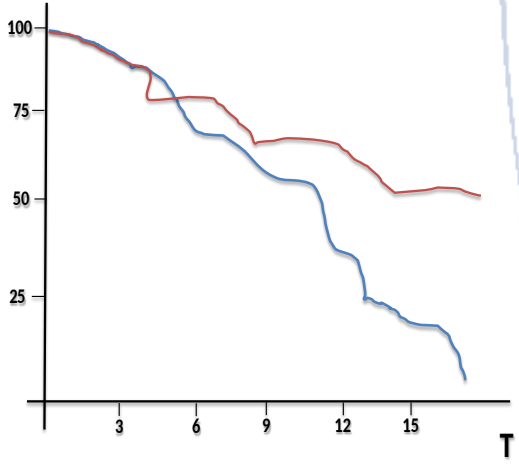


Figure 3. Subgroup Analysis of Progression-free Survival.

HR





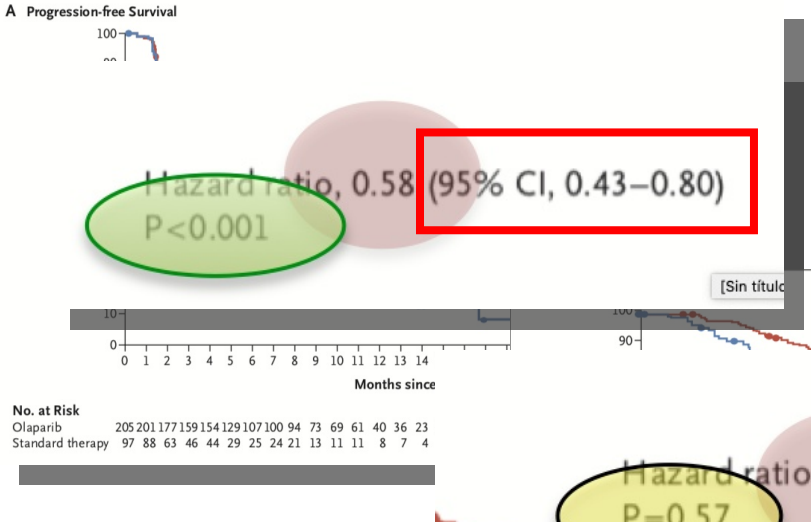
0 1 ∞

Mejor B Mejor A

ORIGINAL ARTICLE

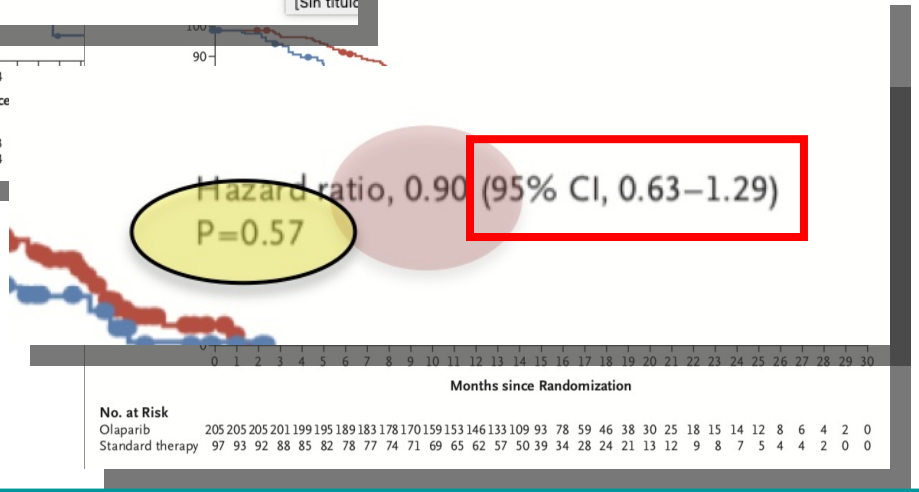
Olaparib for Metastatic Breast Cancer in Patients with a Germline *BRCA* Mutation

Mark Robson, M.D., Seock-Ah Im, M.D., Ph.D., Elżbieta Senkus, M.D., Ph.D.,



Olaparib es mejor

Pero…



Ya sabemos entender la estadística

$p < 0,05$

HR

IC = Intervalo de confianza

ORIGINAL ARTICLE

Olaparib for Metastatic Breast Cancer in Patients with a Germline *BRCA* Mutation

Mark Robson, M.D., Seock-Ah Im, M.D., Ph.D., Elżbieta Senkus, M.D., Ph.D.,

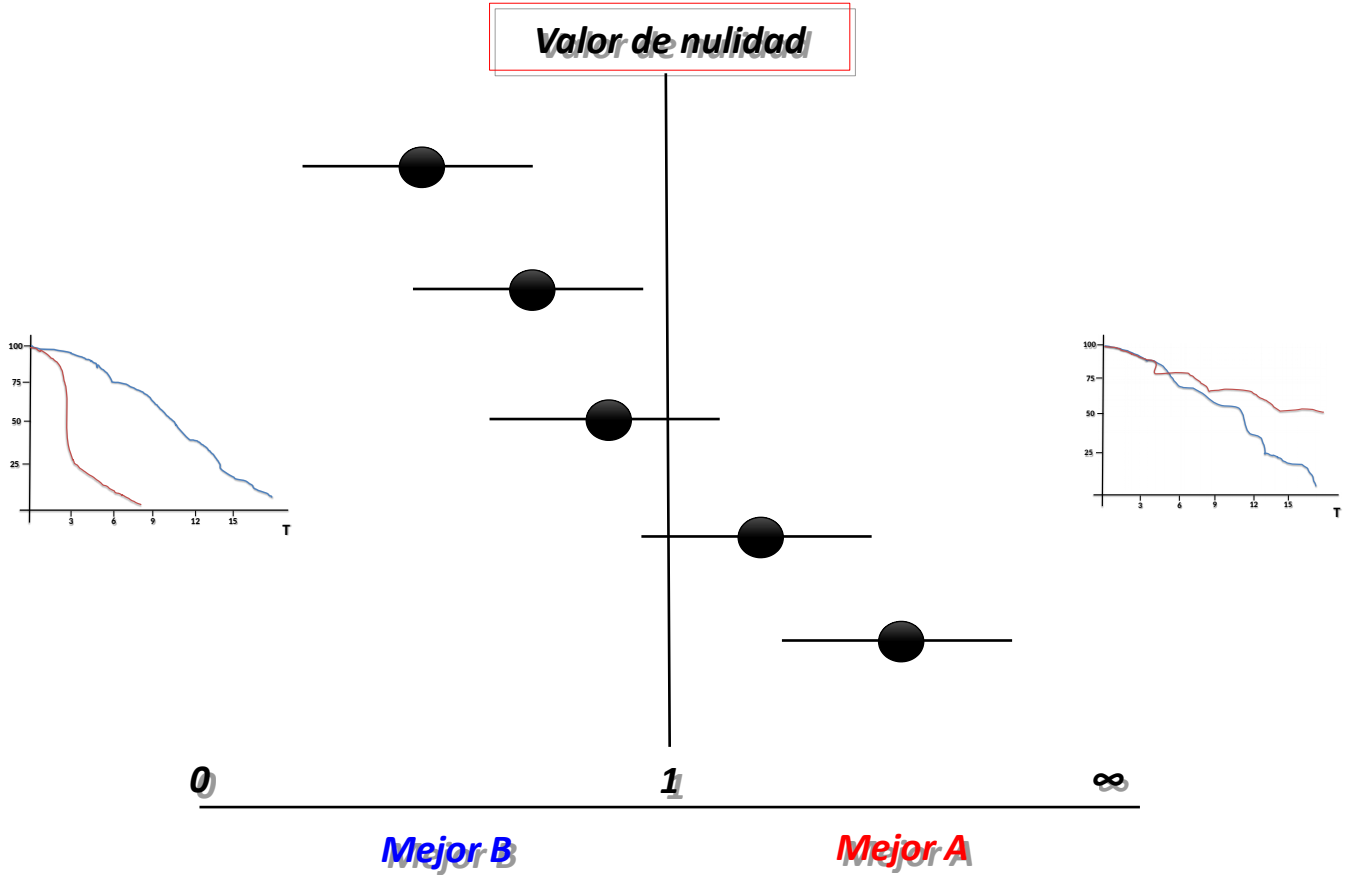
METHODS

We conducted a randomized, open-label, phase 3 trial in which olaparib monotherapy was compared with standard therapy in patients with a germline *BRCA* mutation and human epidermal growth factor receptor type 2 (HER2)–negative metastatic breast cancer who had received no more than two previous chemotherapy regimens for metastatic disease. Patients were randomly assigned, in a 2:1 ratio, to receive olaparib tablets (300 mg twice daily) or standard therapy with single-agent chemotherapy of the physician's choice (capecitabine, eribulin, or vinorelbine in 21-day cycles). The primary end point was progression-free survival, which was assessed by blinded independent central review and was analyzed on an intention-to-treat basis.

RESULTS

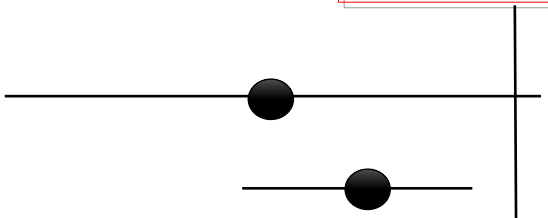
Of the 302 patients who underwent randomization, 205 were assigned to receive olaparib and 97 were assigned to receive standard therapy. Median progression-free survival was significantly longer in the olaparib group than in the standard-therapy group (7.0 months vs. 4.2 months; hazard ratio for disease progression or death, 0.58; 95% confidence interval, 0.43 to 0.80; P<0.001). The response rate was 59.9% in the olaparib group and 28.8% in the standard-therapy group. The rate of grade 3 or higher adverse events was 36.6% in the olaparib group and 50.5% in the standard-therapy group, and the rate of treatment discontinuation due to toxic effects was 4.9% and 7.7%, respectively.

HR

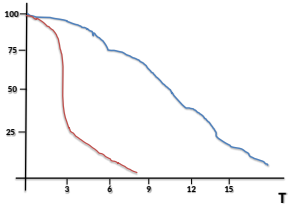


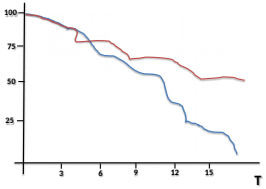
HR

Valor de nulidad



¿Cuál es mejor?





0 **1** **∞**

Mejor B **Mejor A**


¿Cómo vamos?

08:00 - 10:30 Sala AUDITORIO ARAO

CURSO 3 - DIRECCIÓN DE INVESTIGACIÓN SEFH

CÓMO REALIZAR INVESTIGACIÓN CLÍNICA EN FARMACIA HOSPITALARIA, PRINCIPIOS BÁSICOS

Modera:

FERNANDO GUTIÉRREZ NICOLÁS
COMPLEJO HOSPITALARIO UNIVERSITARIO DE CANARIAS, SANTA CRUZ DE TENERIFE

Ponencias:

HERRAMIENTAS (DIGITALES Y ANALÓGICAS) DE AYUDA EN LA ORGANIZACIÓN DE UNA CARRERA INVESTIGADORA Y TRABAJO EN RED Y NOCIONES EN ESTADÍSTICA
FERNANDO GUTIÉRREZ NICOLÁS
COMPLEJO HOSPITALARIO UNIVERSITARIO DE CANARIAS, SANTA CRUZ DE TENERIFE

DISEÑO Y PRESENTACIÓN DE UN PROYECTO DE INVESTIGACIÓN
ANA HERNÁNDEZ GUÍO
FUNDACIÓN JIMÉNEZ DÍAZ, MADRID

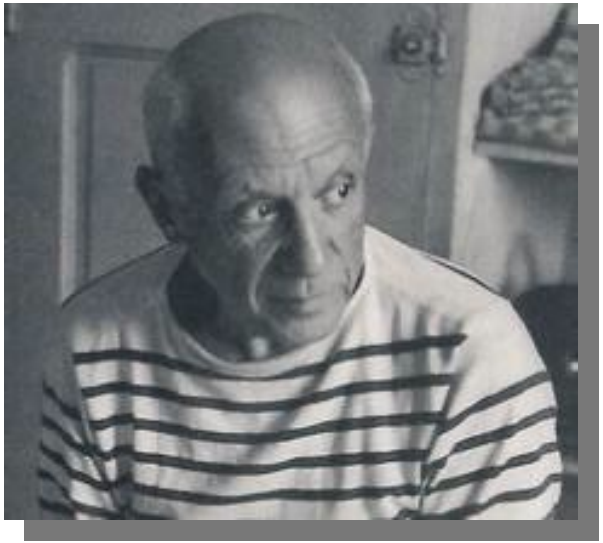
CUADERNO DE RECOGIDA DE DATOS Y REDCAP
BLANCA ANAYA BAZ
RESPONSABLE DE ESTUDIOS DE INVESTIGACIÓN DE LA SEFH, CÁDIZ

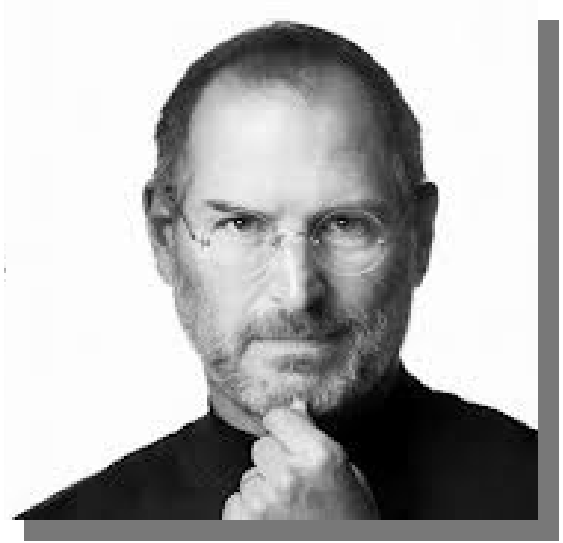
REALIZACIÓN DE UN PÓSTER, CALIDAD EN EL CONTENIDO Y EL DISEÑO GRÁFICO
ANXO FERNÁNDEZ FERREIRO
HOSPITAL CLÍNICO UNIVERSITARIO DE SANTIAGO, SERGAS- IDIS

REDACCIÓN/PUBLICACIÓN DE UN ARTÍCULO CIENTÍFICO Y MANEJO DE GESTORES BIBLIOGRÁFICOS
MARTA MIARONS FONT
HOSPITAL DE VIC, BARCELONA

¿Qué es lo importante?

¿Qué es lo importante?



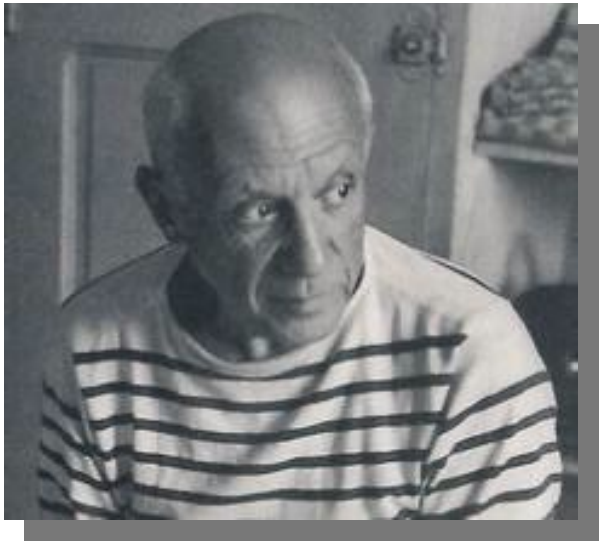


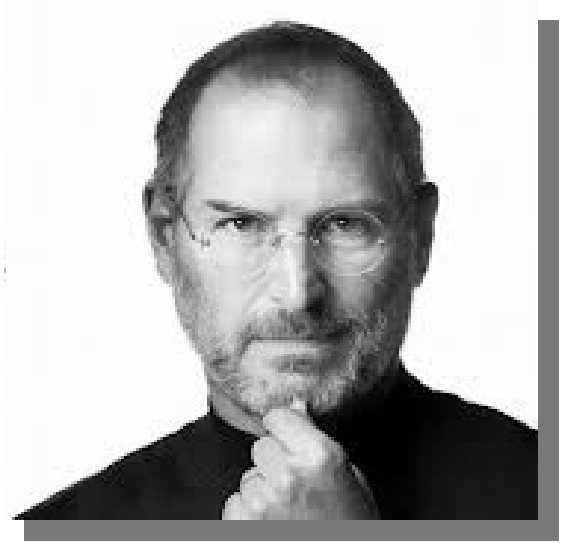
Los buenos artistas crean y los genios copian

¿Cuantos artículos lees a la semana?

1 → 200 en la residencia

¿Qué es lo importante?





Los buenos artistas crean y los genios copian

Los verdaderos genios terminan los trabajos

- **Idea**

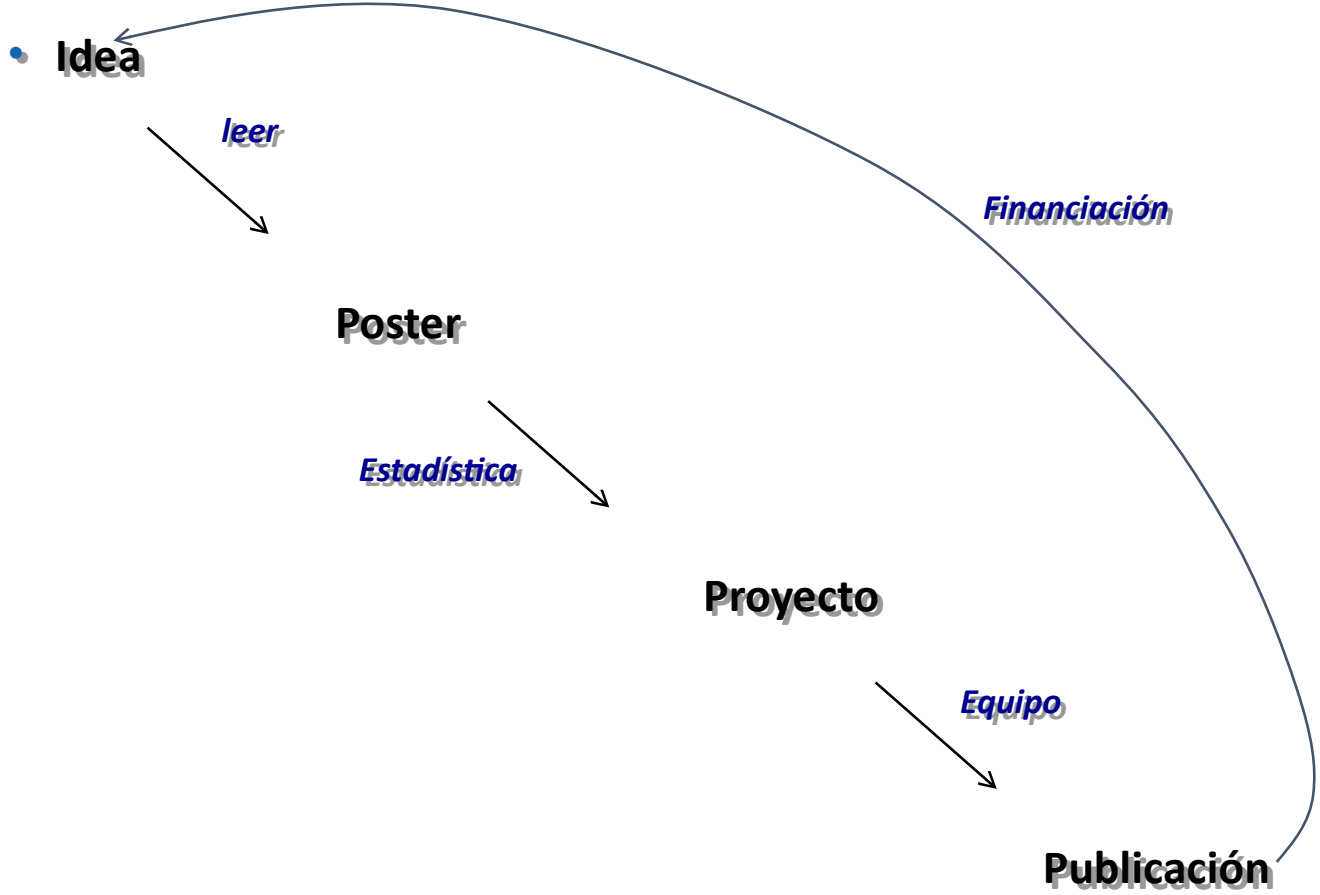
Poster

Proyecto

Publicación

¿Qué es lo importante?

¿La herramienta digital más potente para la investigación?


Idea
leer
Financiación
Poster
Estadística
Proyecto
Equipo
Publicación

- Idea

leer

Financiación

Poster

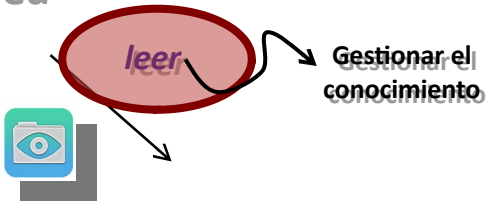
Estadística

Proyecto

Equipo

Publicación

- Idea



Gestionar el conocimiento

Financiación

Poster

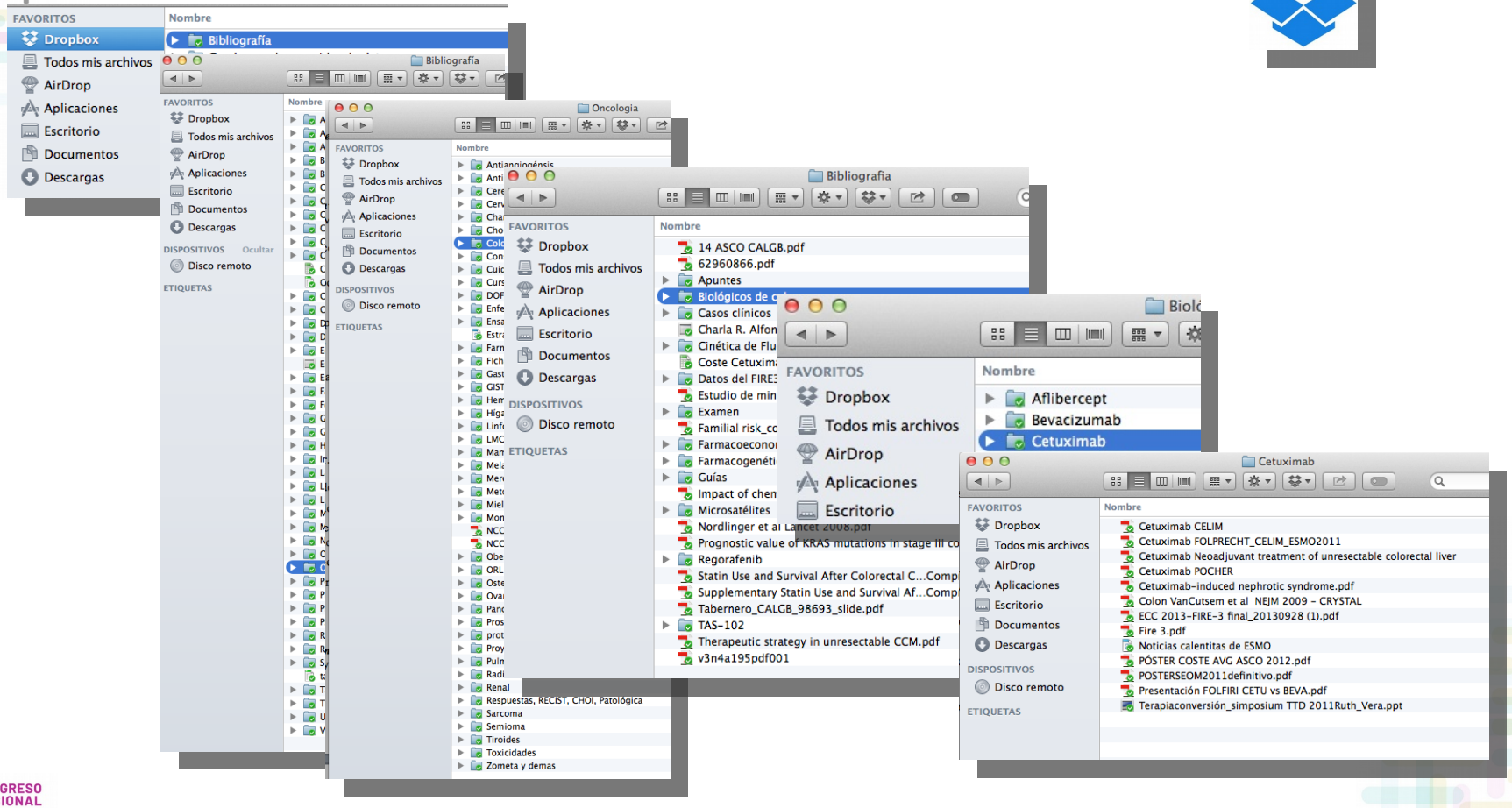
Estadística

Proyecto

Equipo

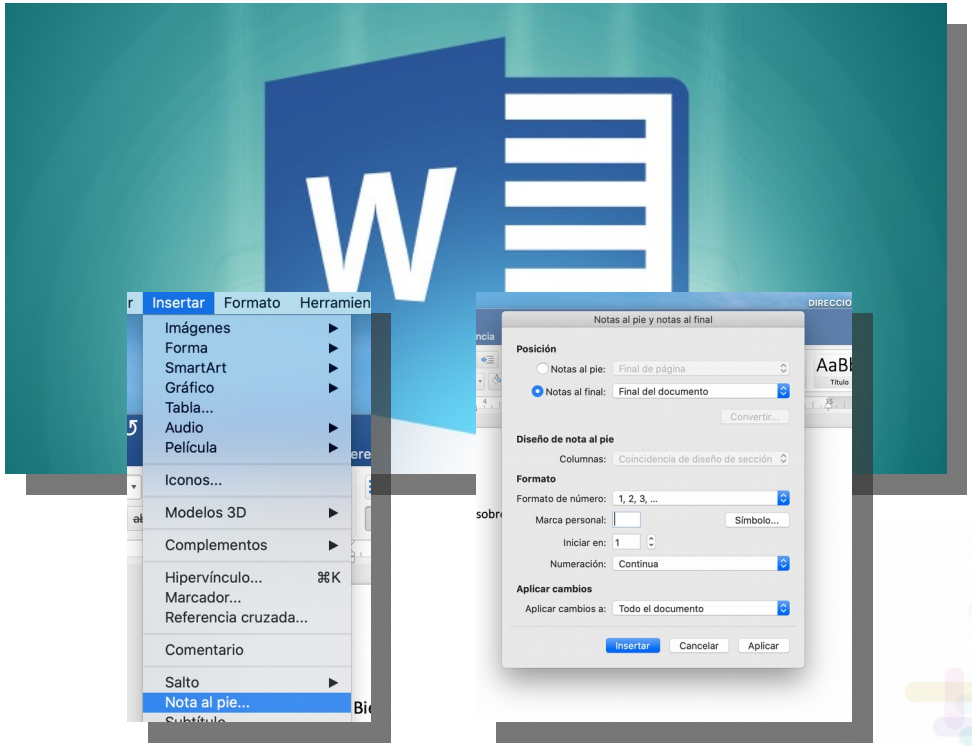
Publicación

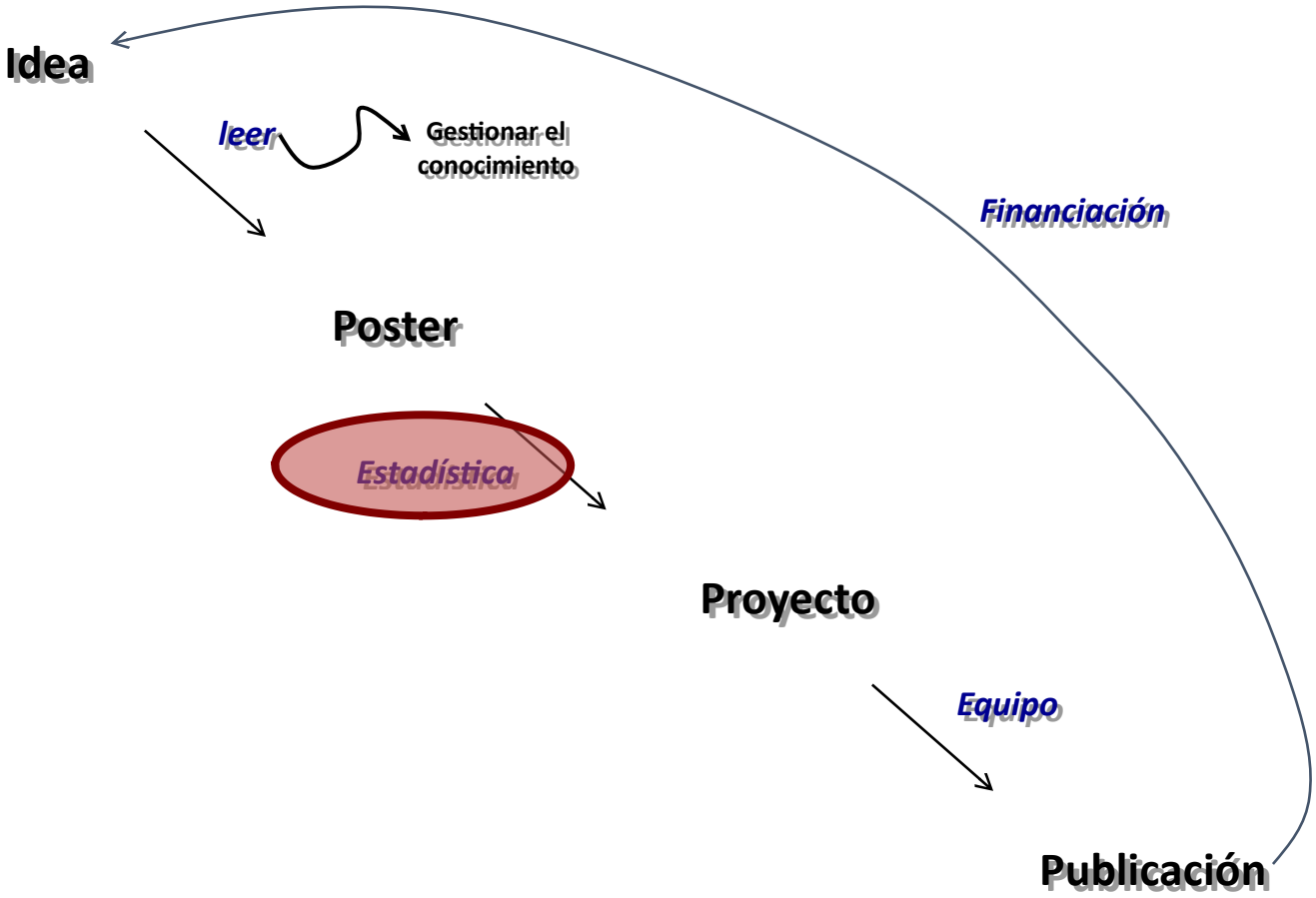
Hay que buscar un orden…



Citas bibliográficas…

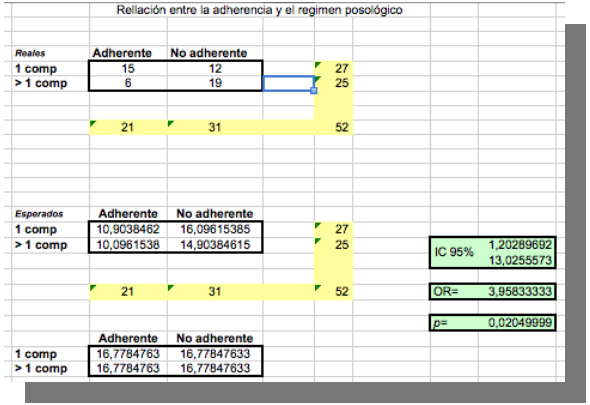
MENDELEY




Idea
leer
Gestionar el conocimiento
Financiación
Poster
Estadística
Proyecto
Equipo
Publicación

La herramienta digital más potente de estadística…

YouTube



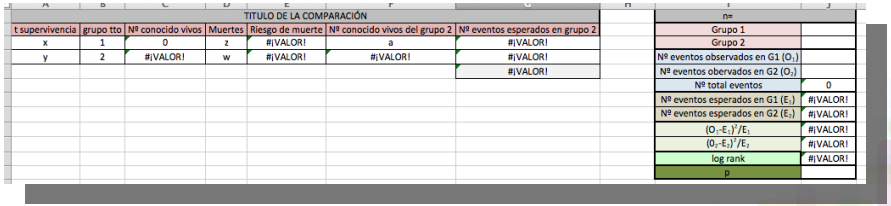
Relación entre la adherencia y el regimen posológico

Reales	Adherente	No adherente	
1 comp	15	12	27
> 1 comp	6	19	25
	21	31	52

Esperados	Adherente	No adherente	
1 comp	10,9038462	16,09615385	27
> 1 comp	10,0961538	14,90384615	25
	21	31	52

IC 95%	1,20289692
	13,0255573
OR=	3,95833333
p=	0,02049999

	Adherente	No adherente
1 comp	16,7784763	16,77847633
> 1 comp	16,7784763	16,77847633



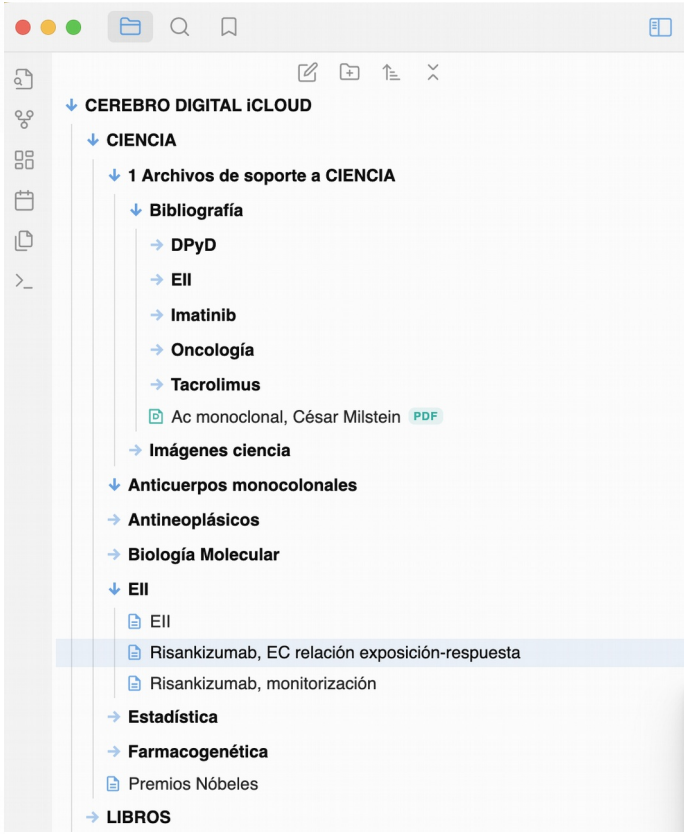
TITULO DE LA COMPARACIÓN

t supervivencia	grupo tto	Nº conocido vivos	Muertes	Riesgo de muerte	Nº conocido vivos del grupo 2	Nº eventos esperados en grupo 2
x	1	0	z	#¡VALOR!	a	#¡VALOR!
y	2	#¡VALOR!	w	#¡VALOR!	#¡VALOR!	#¡VALOR!
						#¡VALOR!

n=	
Grupo 1	
Grupo 2	
Nº eventos observados en G1 (O_1)	
Nº eventos observados en G2 (O_2)	
Nº total eventos	0
Nº eventos esperados en G1 (E_1)	#¡VALOR!
Nº eventos esperados en G2 (E_2)	#¡VALOR!
$(O_1-E_1)^2/E_1$	#¡VALOR!
$(O_2-E_2)^2/E_2$	#¡VALOR!
log rank	#¡VALOR!
p	

¿Qué es lo importante?

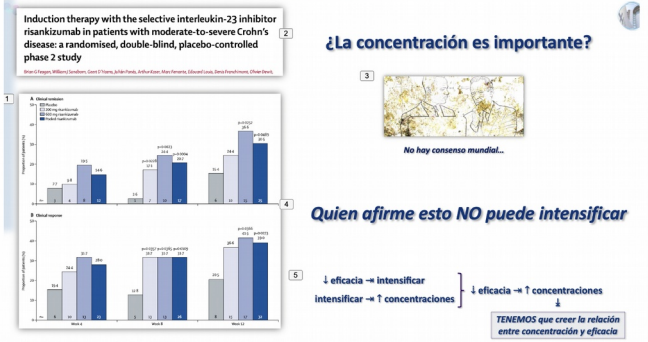
Tomar notas y relacionarlas



Risankizumab, EC relación exposición-respuesta

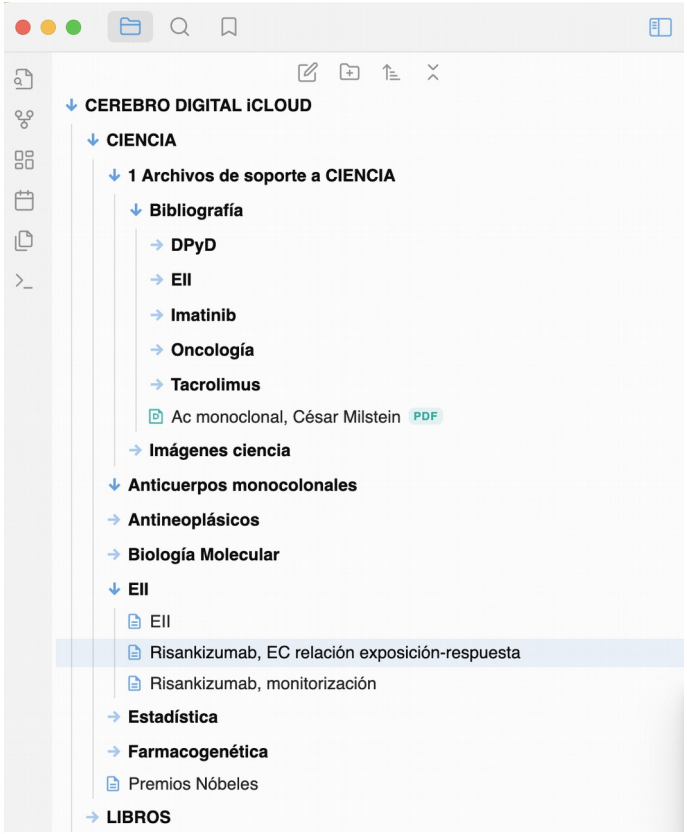
Para analizar la posología, la eficacia y la relación exposición-respuesta del Risankizumab en Enfermedad de Crohn, hemos de diferenciar dos etapas del tratamiento: la inducción y el mantenimiento. En la inducción se inicia el tratamiento con altas dosis e intervalos de administración cortos, con el objetivo de obtener concentraciones plasmáticas del fármaco elevadas de forma temprana y controlar rápidamente la patología. Posteriormente, en el mantenimiento se reduce la magnitud de la dosis con respecto a la inducción y se amplía el intervalo de administración. El objetivo de esta segunda fase es mantener en el tiempo las concentraciones plasmáticas obtenidas en la inducción y con ello la remisión clínica del paciente. Por lo tanto, la relación entre concentraciones plasmáticas y eficacia del fármaco, es una relación fundamental, y es la que hemos revisado en el presente documento.

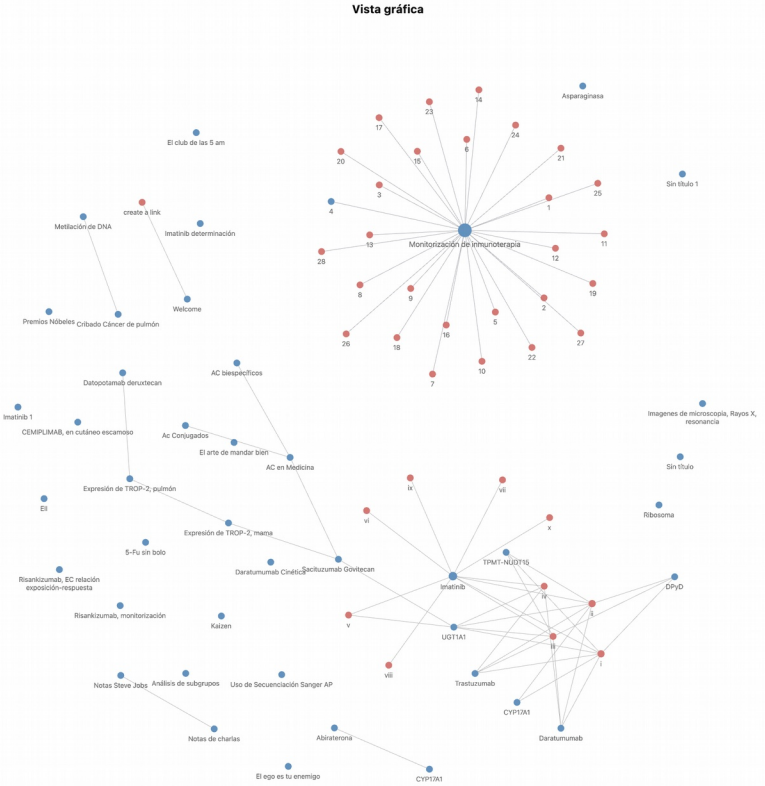
En cuanto a la **relación exposición-respuesta** de risankizumab en Enfermedad de Crohn en la inducción del tratamiento, en el ensayo de fase II NCT02031276, 121 pacientes fueron aleatorizados a recibir en semanas 0, 4 y 8 inducción intravenosa con placebo, risankizumab 200 mg o 600 mg. Los pacientes tratados con inducción de 600 mg de risankizumab mostraron mayores tasas de respuesta en semana 12 basadas en CDAI < 150 frente a 200 mg y placebo Risankizumab, Fase II Faegan, Inducción 600 vs 200.pdf(2).



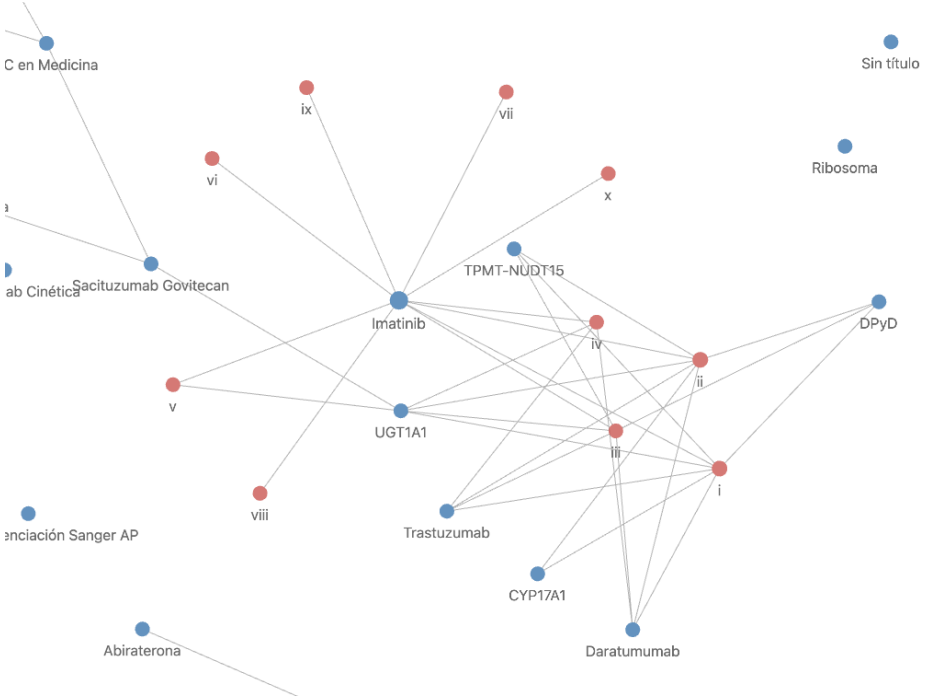
Posteriormente, se realizaron dos fases III también de inducción (ADVANCE Y MOTIVATE). Dado que en el fase II NCT02031276 se evidenció mayor respuesta con mayor dosis, en los

Tomar notas y relacionarlas

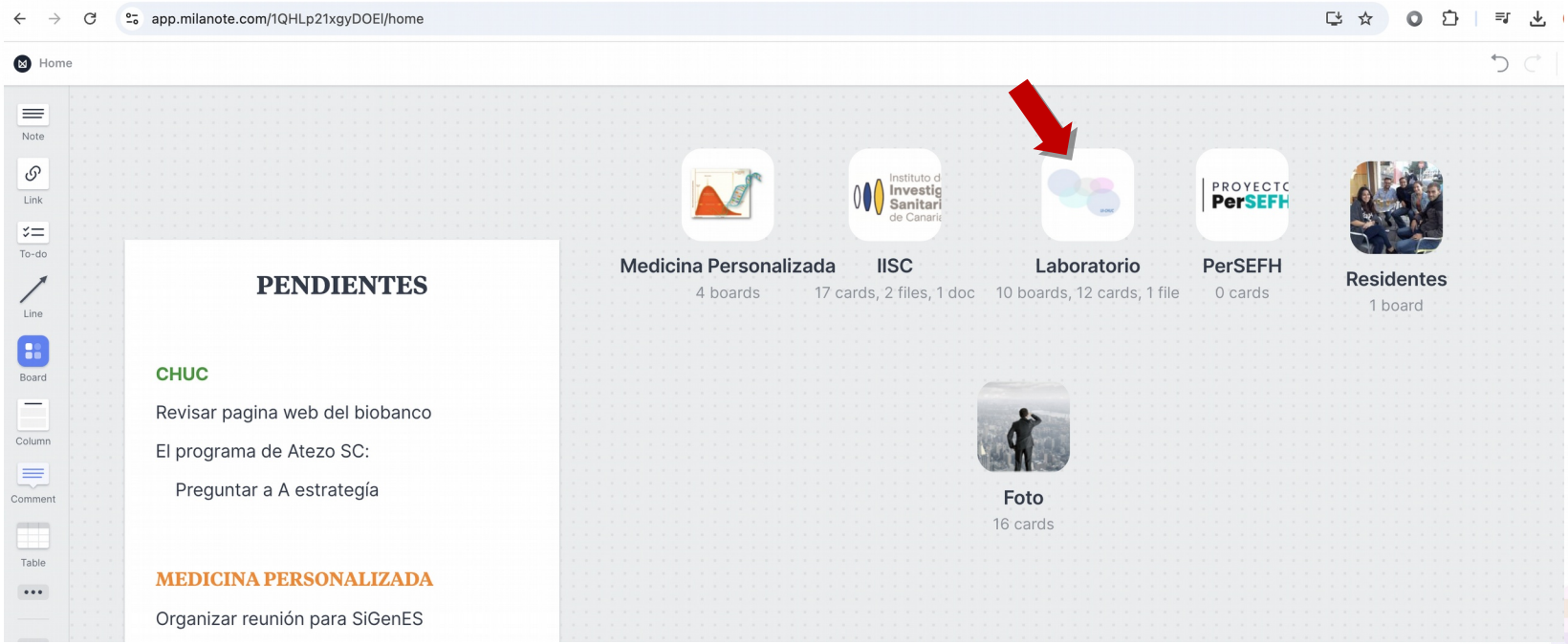




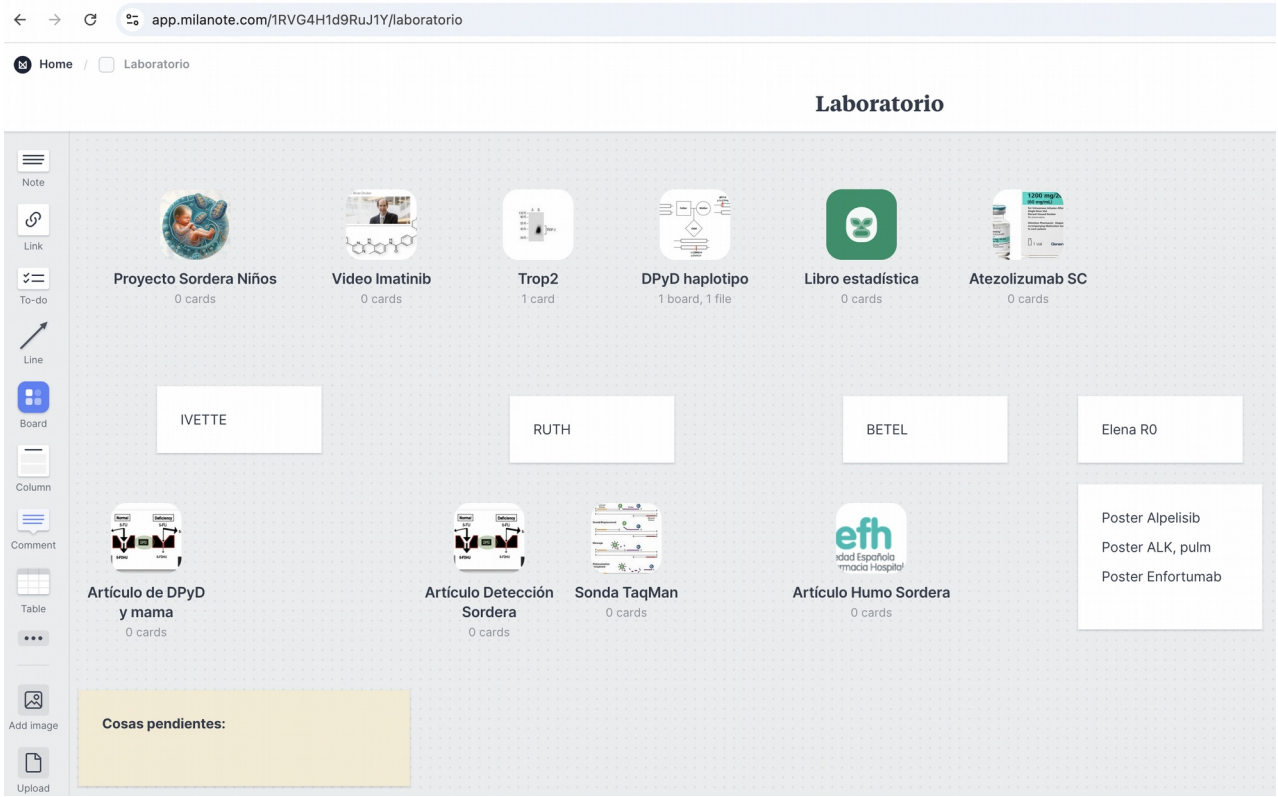
Tomar notas y relacionarlas



Cuadro de mandos



Cuadro de mandos



Herramienta…







¿Qué es lo importante?

Leer…

100 horas
22 días de trabajo

6 meses de escritura

Las herramientas digitales dan oportunidad de visión…

La visión facilita la inspiración…

Qué es lo importante…

A CORUÑA
17-19 OCT 24

Gracias por su atención

@fgunico

fgunico@Gmail.com

69 CONGRESO NACIONAL
SOCIEDAD ESPAÑOLA DE FARMACIA HOSPITALARIA

sefh Sociedad Española de Farmacia Hospitalaria