

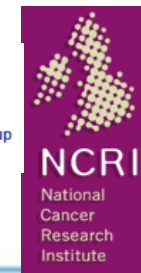


Solo 2



Study of OLoaparib in Ovarian Cancer

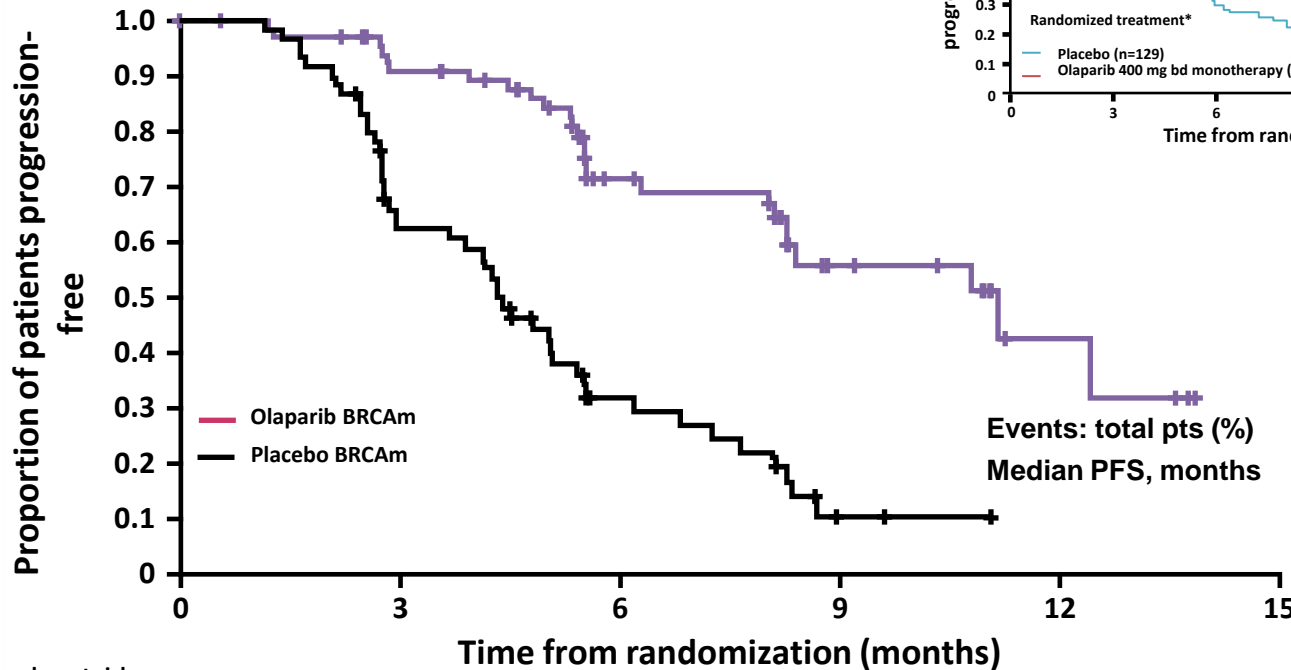
A Phase III Randomised, Double Blind, Placebo Controlled, Multicentre Study of Olaparib Maintenance Monotherapy in Platinum Sensitive Relapsed BRCA Mutated Ovarian Cancer Patients who are in Complete or Partial Response Following Platinum based Chemotherapy



Study 19: Olaparib maintenance therapy in platinum-sensitive relapsed ovarian cancer

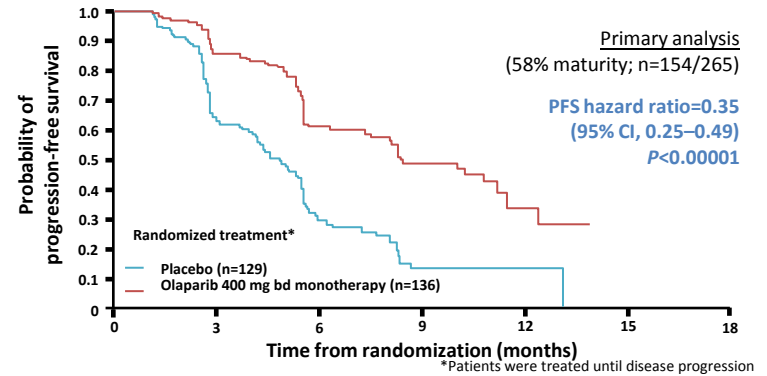
Patients were randomized after response to platinum-based chemotherapy

PFS by BRCAm status



Number at risk

| | | | | | | |
|----------------|----|----|----|----|---|---|
| Olaparib BRCAm | 74 | 59 | 33 | 14 | 4 | 0 |
| Placebo BRCAm | 62 | 35 | 13 | 2 | 0 | 0 |



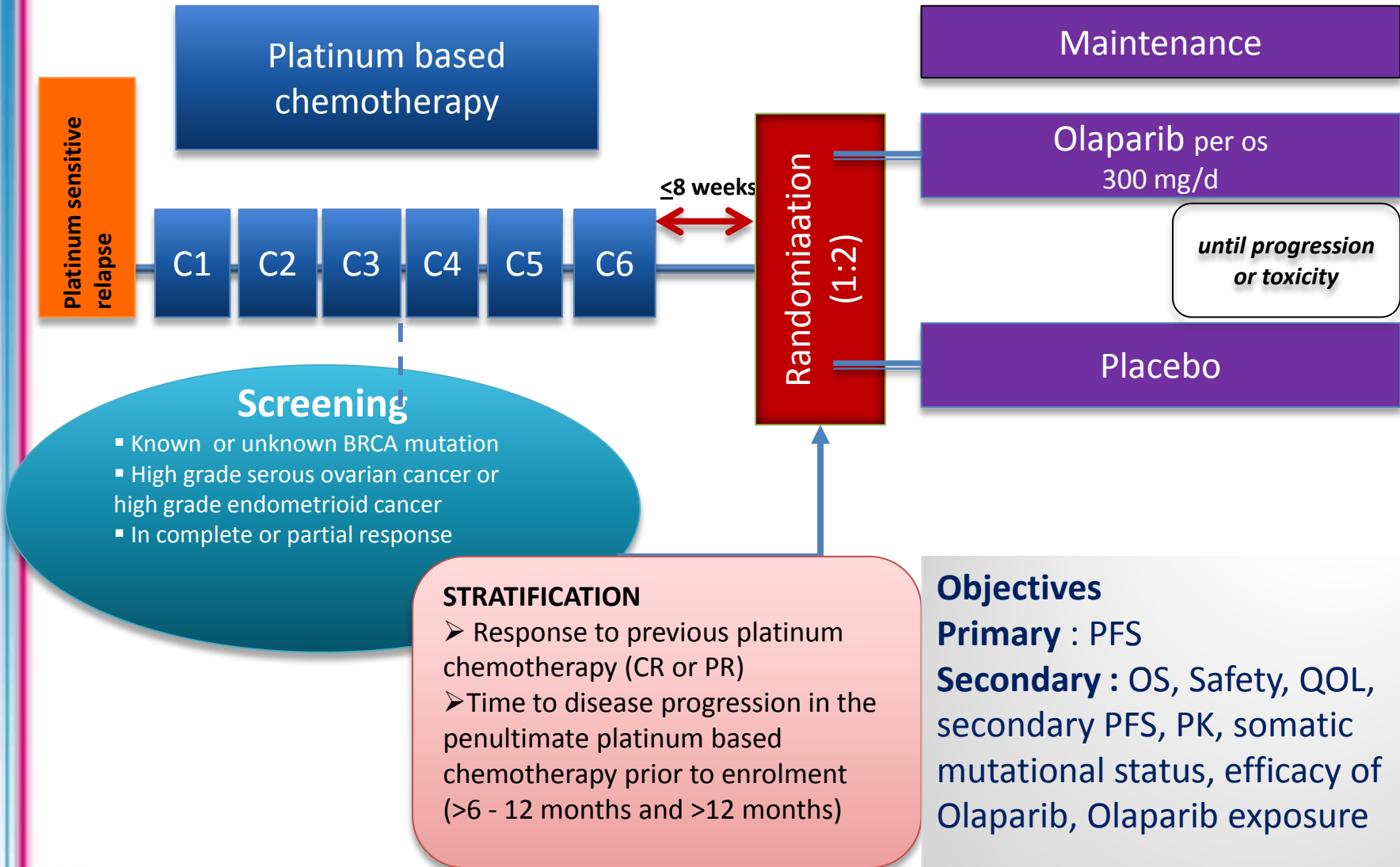
| BRCAm (n=136) | |
|---|--------------|
| Olaparib | Placebo |
| 26:74 (35.1) | 46:62 (74.2) |
| 11.2 | 4.3 |
| HR=0.18 95% CI (0.11, 0.31); P<0.00001 | |

▶ 82% reduction in risk of disease progression or death with olaparib

Patient population

- ▶ Patients with a Platinum sensitive relapse (PSR) high grade serous ovarian cancer with a BRCA mutation or high grade endometrioid cancer
- ▶ At randomization patients will be in complete or partial response following completion (a minimum of four treatment cycles) of platinum-based chemotherapy.
- ▶ Patients must have completed at least two previous lines of platinum based therapy (carboplatin or cisplatin) before entry to the study and must be considered platinum sensitive after the penultimate-based chemotherapy
- ▶ Patients must not have received Bevacizumab during the chemotherapy course immediately prior to randomization.
- ▶ Cytoreductive surgery prior to the last chemotherapy regimen is allowed as long as it is completed before the end of the chemotherapy regimen.
- ▶ Patients with a known BRCA mutation/s from germline (i.e. blood) or a diagnostic tumour* specimen, prior to randomisation can enter the study based on this result.

Study design



Timelines

Global Phase III study

- 17 countries
- 8 GCIIG Groups (GINECO, AGO ,DGOG, MITO, MANGO, NCRI, GOG, JGOG)
- ~80 sites

440 patients to recruit 264 patients with BRCA mutation

4 patients randomised

Recruitment
18 months

158 PFS Events

PFS2
and
OS Follow up

FSI
September
2013!

LSI
March 2015

Primary analysis
28 Jan 2018

Final OS analysis (≥60% mature OS data)
3 Jun 2020

