

Central and Eastern European
Gynecologic Oncology Group



ENGOT-OV16 / NOVA



Phase 3 Randomized Double-Blind Trial of Maintenance with Niraparib Versus Placebo in Patients with Platinum Sensitive Ovarian Cancer

NCT01847274

Sponsor: Tesaro

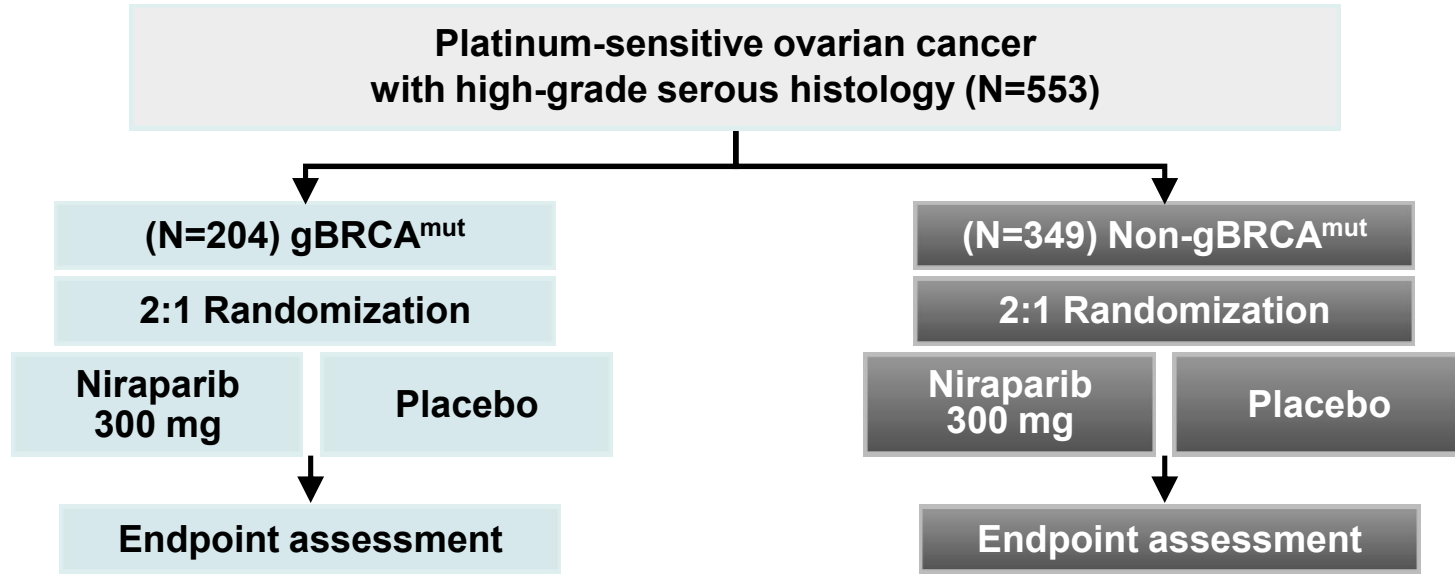
ENGOT Lead: NSGO

Primary Investigators

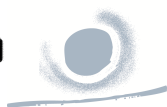
Mirza (ENGOT); Matulonis (US)

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Primary Endpoint	PFS in gBRCA^{mut} and non-gBRCA^{mut} cohorts (HRD positive subset followed by overall)
Key Secondary Endpoints	<ul style="list-style-type: none"> • Overall survival (OS) • Patient-reported outcomes (PRO) • Chemotherapy-free interval (CFI) • Safety and tolerability • PFS2 • Evaluation of QTc



ENGOT Group	No. of sites	Randomised gBRCA	Randomised non-gBRCA
NSGO (DK, N, SE)	9	22	52
AGO (Germany)	13	22	30
AGO (Austria)	3	3	3
BGOG (Belgium)	5	6	12
GEICO (Spain)	7	14	34
GINECO (France)	7	18	29
MaNGO & MITO (Italy)	8	14	5
NCRI (UK)	9	7	24
ISGO (Israel)	8	10	8
CEEGOG	1	3	3
ENGOT TOTAL	71	119 (58%)	200 (57%)
US	39	59	95
Canada	9	21	44
Poland, Hungary	7	3	10
TOTAL	127	204	349

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Status

- If events reached, planned to be submitted for ASCO 2016 as LBA
- TR sub-study proposals are invited