A randomized trial of atezolizumab, niraparib and bevacizumab combination for patients with recurrent ovarian cancer.

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Sponsor: NSGO

Study Chair: Mansoor Raza Mirza

FPI (expected): Q3 2019

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- CFI of 1-6 months of last receipt of chemotherapy
  OR
- CFI of <1 month of last receipt of chemotherapy
- Patients must have received platinum-containing therapy
- Max of 5 series of prior therapies for the relapsed disease though max 2 series of prior therapies for plat-resistant relapse.
- Patients may have received bevacizumab.
- Patients may have received PARP inhibitor
- No prior immunotherapy.

Standard of Care
Mono-chemotherapy with/without bevacizumab

1:2 randomization
N 168

Non-chemo experimental arm
Bevacizumab-Atezolizumab-Niraparib

Stratification
- Prior use of PARPi (yes/no)
- Prior use of bevacizumab (yes/no)
- treatment free interval to prior therapy (upto 4 wks versus >4 wks)
- No. of lines of therapy as platinum resistant disease. (one versus more)

Treat until progression of disease

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Objectives

Primary objectives:

- Compare Overall Response Rate (ORR) according to RECIST (ORR) of niraparib-bevacizumab-atezolizumab against Standard of care (SoC) therapy.
- In hierarchal pattern if ORR is positive, progression-free survival (PFS) will be evaluated

Main secondary objective:

- Overall survival (OS)
- Duration of response

Secondary objectives:

- Safety and tolerability of atezolizumab when given in combination with niraparib-bevacizumab.
- PFS according to trial stratification factors.
- Objective response rate according to irRECIST (irORR)
- Disease control rate (DCR) (CR+PR+SD)
- Patient Reported Outcomes (PROs)
- TFST, PFS2, TSST

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Treatment arms

- **Arm A:**

chemotherapy alone (weekly paclitaxel or PLD or gemcitabin)
or
chemotherapy + bevacizumab (only bevacizumab naïve patients can receive bevacizumab).

- **Arm B:**

Niraparib 200mg PO once daily until disease progression.
Bevacizumab 15mg/kg IV q 21 days until disease progression
Atezolizumab until progression (dose to be added)