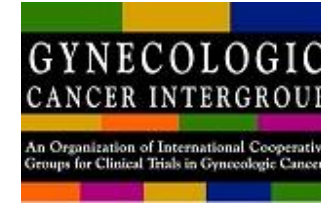




Ongoing Trials – status update

MITO 23 ENGOT Ov-32



Randomized phase III trial on Trabectedin (ET 743) vs clinician's choice chemotherapy in recurrent ovarian, primary peritoneal or fallopian tube cancers of BRCA mutated or BRCAness phenotype patients

**Recurrent ovarian,
primary peritoneal or
fallopian tube cancers
of BRCA mutated or
BRCAness phenotype
patients**

1° Endpoint: OS
2° Endpoints: PFS, RR, Duration of Response, Toxicity, Ca125 response, QOL

Random1.1

**STRATIFICATION
CRITERIA:
Measurable Disease
Platinum Sensitivity
Number of Previous
CHT Lines
Mutational status**

**II line chemotherapy
(physician choice):**

- PLD 40 mg/mq d1 q28;
- Topotecan 4 mg/mq d1,8,15 q 28
- Weekly Paclitaxel 80 mg/mq d1,8,15 q28
- Gemcitabine 1000 mg/mq gg1,8,15 q28
- Carboplatin AUC 5 g 1 q 21

**Trabectedin 1.3 mg/mq d1 q 21
in 3 hours (central line)**



Ongoing Trials – status update

MITO 23 ENGOT Ov-32



Randomized phase III trial on Trabectedin (ET 743) vs clinician's choice chemotherapy in recurrent ovarian, primary peritoneal or fallopian tube cancers of BRCA mutated or BRCAness phenotype patients

Lead group: **MITO**

Academic trial -**NCI of Milano sponsor**

Data center: NCI of Milan

Trabectedin provided

Planned No. of patients: **244**

No. of already recruited patients: **224**

Timeline: **FPI Feb 2016 , LPI Q4 2018**

Enrollment by Group

GROUP	N. Patients
MITO	203
MANGO	21
Total	224