ENGOT ONGOING TRIALS – STATUS October 2015

ENGOT-ov-1/MITO-8 – Leading Group: MITO
Randomized trial of PLD followed by paclitaxel/carboplatin versus paclitaxel/carboplatin followed by PLD in intermediate platin sensitive recurrent ovarian cancer (S. Pignata)
Number of patient accrued: 215
Number of patients needed: 253
Participating member groups: MITO - MaNGO - BGOG - AGO Germany (no longer recruiting)

ENGOT-ov5 - Leading group: MaNGO
Phase III multicenter, randomized study of Trabectedin plus Pegylated Liposomal Doxorubicin (PLD) versus Carboplatin plus PLD in patients with ovarian cancer progressing within 6-12 months of last platinum (N. Colombo) / study reactivated
Number of patient accrued: 229 randomised / recruitment continues
Number of patients needed: 588
Participating members: AGO, MaNGO, FORTC, NOGGO, BGOG, NSGO, GEICO, NCRI, ECOG

ENGOT-ov6 – Leading group: A-AGA
A phase 3, Randomized, Double-Blind trial of Pegylated Liposomal Doxorubicin (PLD) Plus AMG 386 or Placebo in Women with Recurrent, Partially Platinum Sensitive or Resistant Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancer (Ch. Marth)
Number of patients accrued: 223
Number of patients needed: 380
Participating member groups: AGO, A-AGO, BGOG, DGCG, MITO, MaNGO, NCRI, Gineco

ENGOT-ov7 - GINECO / Alienor
Randomized open label Phase II trial of Bevacizumab plus weekly Paclitaxel followed by Bevacizumab monotherapy maintenance versus weekly paclitaxel followed by observation in patients with relapsed sex-cord-stromal tumors.
Number of patient accrued: 42 / recruitment continues
Number of patients needed: 60
Participating members: Gineco (leading group), AGO

ENGOT-ov8 - Leading group: NOGGO
Single arm multicenter phase-II trial for Catumaxomab and chemotherapy in patients with recurrent ovarian cancer to investigate the feasibility and clinical activity of initial IP Catumaxomab followed by chemotherapy regimens. (J. Sehouli) / was stopped
Date of activation: 2012
Number of patient Number of patient accrued: 235
Number of patients needed: 51
Participating members: NOGGO, AGO, A-AGO, BGOG, MaNGO, NSGO
ENGOT-ov11 - Leading group: BGOG
A multinational, Randomised, Open-label, Phase 3 Study of MEK162 vs. Physician's Choice Chemotherapy in Patients with Recurrent of Persistent low-grade Serous Carcinomas of the Ovary, Fallopian Tube or Primary Peritoneum. (I. Vergote). / Activated

Number of patient accrued: 235 / recruitment ongoing
Number of patients needed: 360
Leading group: BGOG
Groups interested: MITO, MaNGO, Gineco, NOGGO, AGO, A-AGO, NSGO, NOGGO, ISGO

ENGOT 13/ICON8 - Leading group: NCRI
An international multi-stage randomised trial of dose-fractionated chemotherapy compared to standard three-weekly chemotherapy, following immediate primary surgery or as part of delayed primary surgery, for women with newly diagnosed epithelial ovarian cancer (J. Ledermann). / Recruitment is well running

Number of patient accrued: 1566
Number of patients needed: 1485
Participating members: NCRI, GEICO, ICORG, SCOTROC, KGOG and Mexico

ENGOT 13/ICON8b - Leading group: NCRI
A study of bevacizumab and weekly dose-dense paclitaxel in ovarian cancer

Number of patient accrued: 1
Number of patients needed: 1170

ENGOT-ov14/ AGO-OVAR 2.20 - Leading group: AGO
A randomised phase II study comparing Caelyx or Topotecan or Gemcitabin with or without Pertuzumab in patients low HER3 mRNA platin-resistant ovarian cancer. (Christian Kurzeder). /

Date of activation: 2012 / recruitment closed in September 2014
Number of patient accrued: 156
Number of patients needed: 220
Participating members: AGO, A-AGO, NSGO, Gineco, GEICO, BGOG, MaNGO, TRSGO

ENGOT-ov15/AGO-OVAR 17 - Leading group: AGO
A prospective randomised Phase III trial to evaluate optimal treatment duration of first-line bevacizumab in combination with carboplatin and paclitaxel in patients with primary epithelial ovarian, fallopian tube or peritoneal cancer. The BOOST (Bevacizumab Ovarian Optiam Standard Treatment) Trial. (J. Pfisterer)

Number of patient accrued: 927 / Recruitment Completed. Results expected in 2017
Number of patients needed: 900
Participating members: AGO, Gineco, NSGO

ENGOT-ov16/NOVA - Leading group: NSGO
Maintenance with Niraparib Versus Placebo in Patients with Platinum Sensitive ovarian Cancer (Manour R. Mirza). / Recruitment is well running

Number of patient accrued: 553 / Recruitment ongoing
Number of patients needed: 360
Participating members: AGO, A-AGO, ISGO, Gineco, GEICO, MaNGO, MITO, NCRI

ENGOT-ov17/MITO 16
Phase III trial with second line chemotherapy +/- Bevacizumab in patients with platinum sensitive ovarian cancer recurrence after Bevacizumab and chemotherapy in the first line. (S. Pignata)

Date of activation: 2013 April
Number of patient accrued: 117 / Recruitment ongoing
Number of patients needed: 400
Participating members: MITO (leading), MaNGO, Gineco, HECOG, SAKK

ENGOT-ov18/AGO-OVAR 2.21
In this trial patients with platinum sensitive recurrent ovarian cancer (more than 6 months platinum-free interval) will be randomised between Carbo/Gem with Bevacizumab versus Carbo/Caelyx with Bevacizumab. (J. Pfisterer) / Recruitment is well running
Date of activation: 2013
Number of patient accrued: 682
Number of patients needed: 654
Participating members: AGO, Gineco

ENGOT-ov19 - GEICO
Phase III multicenter randomised study of BIBF 1120 versus placebo combined standard chemotherapy (PLD/Carboplatinum) in platinum resistant and platinum -sensitive disease (Jose Maria del Campo). / Trail is on Hold
Date of activation: 2013
Number of patient accrued: 600
Number of patients needed: 900
Participating members: GEICO, NSGO, GOG, Gineco, BGOG, MaNGO, MITO, NCRI, DGOG

ENGOT-ov20 Desktop 3 - Leading group: AGO
Randomised trial investigating secondary debulking versus no-secondary debulking in platin sensitive disease. (A. du Bois)
Number of patient accrued: 408 / Last patient recruited in March 2015 / OS analysis planned for 2019
Number of patients needed: 408
Participating members: AGO, A-AGO, BGOG, MITO, Gineco, NSGO, GEICO, NCRI, SGCTG (KGOG)

ENGOT-ov21 / Solo2-3 - Leading group: GINECO
Study of Olaparib on Ovarian Cancer (Eric Pujade-Lauraine).
Number of patient accrued: 295 randomised out of 603 / Recruitment finished October 2014
Number of patients needed: 440
Participating members: AGO, DGOG, MITO, ISGO, NCRI, MANGO.

ENGOT-ov22 - Leading group: NOGGO
Expression IV- What do primary and recurrent ovarian cancer (OC) patients expect from maintenance therapy?
Number of patient accrued: 1248 / Still open till March 2016 for interested groups
Number of patients needed: 200-300
Participating members: NOGGO

ENGOT-ov23: GINECO EWOC-1 Leading group: NOGGO
Multicenter, randomized trial of carboplatin +/-paclitaxel in vulnerable elderly patients with stage IIB- IV advanced ovarian cancer / Recruitment is running
Number of patient accrued: 68
Number of patients needed: 240

ENGOT-ov24 - AVANOVA: NSGO
Niraparib and/or Niraparib-bevacizumab combination against bevacizumab alone in Women with platinum-sensitive epithelial ovarian, fallopian tube, or primary peritoneal cancer
Number of patient accrued: 132
Number of patients needed: 612
Participating members: ISGO, MITO, GEICO
ENGOT-ov25 - PAOLA: GINECO
Randomized, Double-blind, Phase III Trial of olaparib vs. placebo in combination with bevacizumab in women following first-line chemotherapy plus bevacizumab for advanced high grade epithelial ovarian, fallopian tube, or primary peritoneal cancer.
Number of patient accrued: 18
Number of patients needed: 612
Participating members: AGO-Austria, AGO-Germany, BGOG, GEICO, NSGO, MANGO, MITO,

ENGOT-ov26 - Leading group: GEICO
Phase 3 Maintenance Study to Evaluate the Efficacy and Safety of Niraparib Versus Placebo in Women Who Have Not Progressed after First Line Chemotherapy for Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer.
Number of patient accrued: 84
Number of patients needed: 530
Participating members: ISGO, MITO, HeCOG, ICORG, NSGO, BGOG, GINECO, SAKK, AGO-Germany, TRGOG.

ENGOT-ov27 - Leading group: BGOG
A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study to Assess the Efficacy and Safety of Farletuzumab (MORAb-003) in Combination with Carboplatin plus Paclitaxel or Carboplatin plus Pegylated Liposomal Doxorubicin (PLD) in Subjects with Low CA125 Platinum-Sensitive Ovarian Cancer
Number of patient accrued: 17
Number of patients needed: 210
Participating members: MITO, GEICO, NOGGO

ENGOT-EN1-I - Leading group: NSGO
Randomized phase II trial of first-line combination chemotherapy with BIBFI 120 or placebo for patients with advanced or recurrent cancer. (Mansoor Raza Mirza) /Study not started yet
Number of patient accrued: First patient planned for March 2016
Number of patients needed: 150
Leading Group: NSGO
Groups interested: MITO, Gineco, NOGGO, AGO, EORTC, BGO

ENGOT-EN2 - Leading group: DGCG
Adjuvant chemotherapy in node negative endometrial carcinoma. (Mansoor Raza Mirza)
Number of patient accrued: 100
Number of patients needed: 678
Participating members: DGCG, NSGO, EORTC, MITO, AGO, A-AGO, NOGGO, BGOG, MaNGO, DGOG
Mayo Clinic and Gothic (Japan) will be cooperating.

ENGOT-EN3 - PALEO- Leading group: NSGO
A randomized phase II trial of Palbociclib in combination with letrozole versus letrozole for patients with oestrogen receptor positive recurrent endometrial cancer.
Number of patient accrued: First patient planned for April 2016
Number of patients needed: 80
Leading Group: NSGO
Groups interested:

ENGOT-GYN1 / SGCTG - NSGO
A phase II trial of a triple angiokinase inhibitor (BIBF1120) in the treatment of patients with recurrent clear cell ovarian cancer. (Mansoor Raza Mirza)
Date of activation: 2013
Number of patient accrued: 1 / Open in UK
Number of patients needed: 90
Participating members: SGCTG (lead group, in cooperation with NSGO), NCRI, EORTC, GINECO
ENGOT-VI/DGOG - GROINSV-2 - Leading group: DGOG
Radiotherapy in vulvar carcinoma with small metastatic sentinel nodes. (A. van der Zee)

Number of patient accrued: 1500
Number of patients needed: 500
Participating members: DGOG, BGOG, NCRI, NSGO, GOG

ENGOT-Cx/BGOG-cxI
A randomized phase II trial of paclitaxel-carboplatin 3-weekly with or without Nintedanib (BIBFI 120) in advanced or recurrent cervical cancer. (I. Vergote)

Date of activation: Q1 / 2013
Number of patient accrued: 23 randomised out of 120
Number of patients needed: 120
Participating members: BGOG, MITO, Gineco, GEICO, NCRI, MaNGO

PAST TRIALS

ENGOT-ov2/BGOG-ov7 - Leading group: BGOG
AMG386/paclitaxel-carboplatin versus paclitaxel/ carboplatin as first-line therapy in advanced ovarian, peritoneal and fallopian tube cancer. (I. Vergote)

Number of patient accrued: 832
Number of patients needed: 2000 (reduced to 1000)
Participating members: BGOG (leading), AGO, A-AGO, GEICO, Gineco, HECOG, MITO, MaNGO (and GOG), DGOG
Closure: 2013

ENGOT-ov3/ Aurelia – Leading group: GINECO
Randomized trial comparing chemotherapy with or without bevacizumab in recurrent platin-resistant ovarian cancer.
Number of patient accrued: 360
Number of patients needed: 360
Participating members: Gineco, AGO, BGOG, DGCG, GEICO, MITO, NSGO, HECOG
Closure: 4/2012 /
Publications:

1. The AURELIA Open-Label Randomized Phase III Trial
Eric Pujade-Lauraine, et al.
Published 17 March 2014, 10.1200/JCO.2013.51.4489
2. Patient-Reported Outcome Results From the Open-Label Phase III
Martin R. Stockler, et al.
Published 31 March 2014, 10.1200/JCO.2013.51.4240

ENGOT-ov4 – Leading group: NOGGO
Perceptions and expectations on clinical management of ovarian cancer European survey: Expression III. (J. Sehouli).
Number of patients accrued: 1776 (closed)
Participating groups: NOGGO, AGO, BGOG, MITO, MaNGO, NCRI, Gineco, GEICO
Publication expected

ENGOT-ov6 – Leading group: A-AGA
A phase 3, Randomized, Double-Blind trial of Pegylated Liposomal Doxorubicin (PLD) Plus AMG 386 or Placebo in Women with Recurrent, Partially Platinum Sensitive or Resistant Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancer. (Ch. Marth). / Study is closed
Number of patients accrued: 223
Number of patients needed: 380
Participating member groups: AGO, A-AGO, BGOG, DGCG, MITO, MaNGO, NCRI, Gineco

ENGOT-ov9 - Leading group: NOGGO
A randomized, double-blind, placebo controlled, multicenter Phase II study to assess the efficacy and safety of Sorafenib added to standard treatment with Topotecan in patients with platinum-resistant recurrent ovarian carcinoma. (J. Sehouli)

Number of patient accrued: 174
Number of patients needed: 174
Participating members: AGO, NOGGO
Closure: 2013 / Data immature yet.

ENGOT-ov10/MITO-7 - Leading group: MITO
First line weekly carboplatin and paclitaxel vs every 3 weeks carboplatin/paclitaxel in patients with ovarian cancer: Phase III multicenter trial. (S. Pignata).
Number of patient accrued: 824 (closed)
Number of patients needed: 800
Participating members: MITO - MaNGO - Gineco - HECOG
Publications: ENGOT.ov10 paper (MITO-7) - ENGOT.ov10 appendix

ENGOT-ov12 - Leading group: MITO
Pathway to diagnosis of ovarian cancer: an observational retrospective multicentre trial. (J. Bryce).
Number of patient accrued: 695 (closed) / Publication in progress
Number of patients needed: xxx
Participating members: MITO, MaNGO, BGOG, Gineco, NOGGO