

MITO Phase III TRIALS

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Liposomal doxorubicin stealth vs carboplatin/paclitaxel in recurrent ovarian cancer patients with platinum-free interval between 6-12 months

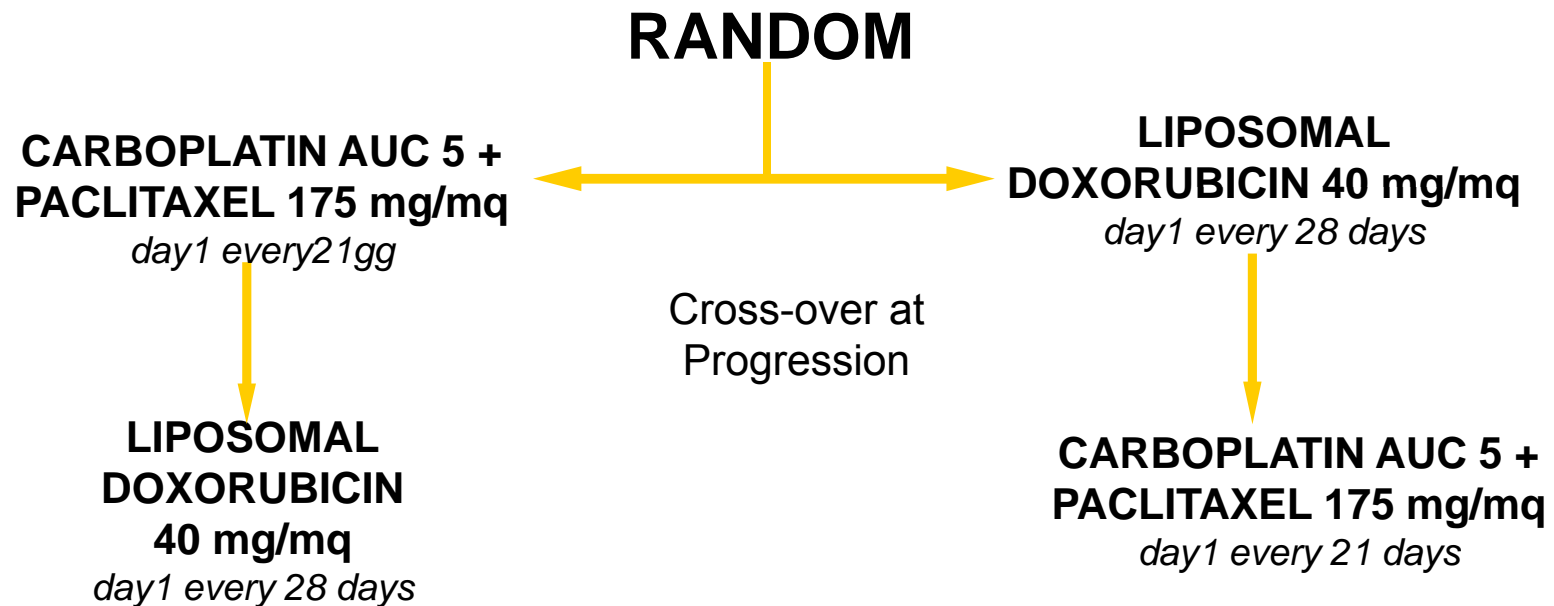
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ENGOT OV-1



Trial design

- The objective of this trial is **the efficacy** determined through analysis of overall survival (OS) of the different sequence (CP→PLD vs PLD→CP) in recurrent ovarian cancer patients with platinum-free interval 6-12 months



Statistics



- Median Overall Survival:
 - expected (control arm): 18 months
 - auspicated (experimental arm): 27 months
- Alpha error: 0.05, bilateral
- Power: 80%
- 193 events (progression) are needed
- 253 patients are to be enrolled (planned in 4 yr)

MITO8

- NCI of Naples is the coordinating centre
- Insurance for Italy (Gerling Italia)
- Only institutional funding for Italy
- First center open September 2008

MITO8 – Groups involved

- MaNGo (ready)
- Belgium (ready)
- AGO (funding application to authority)
- NOGGO
- Others?



First line weekly carboplatin and
paclitaxel vs every 3 weeks
carboplatin/paclitaxel in patients with
ovarian cancer:

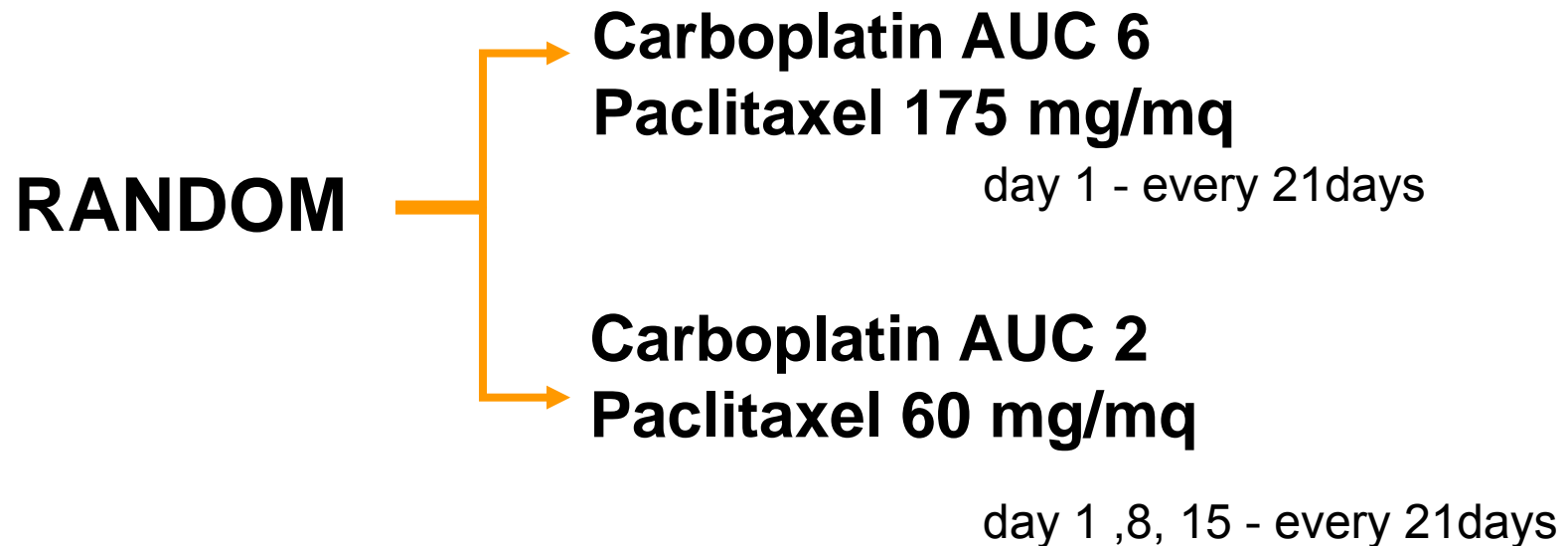
Phase II multicenter trial

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Trial design

- Aim of the trial is to compare the **quality of life** of weekly (experimental arm) versus every 3 weeks administration (standard arm) of carboplatin plus paclitaxel administration of the same drugs in 1^o-line advanced ovarian, tubal and peritoneal cancer



Statistics



- Phase 3 open-label multicentre trial
- Quality of life as primary end-point
 - Difference in FACT-O after 9 weeks: 30%
- Overall survival, PFS, activity and toxicity are the secondary end-points.
- Alpha error: 0.05, bilateral
- Power: 80%
- # patients to enroll: 400

MITO7

- NCI of Naples is the coordinating centre
- Insurance for Italy (Gerling Italia)
- First center open September 2008
- After JGOG results at ASCO discussion on amendment (PFS as main objective)
- The expected duration of the study: 20 months

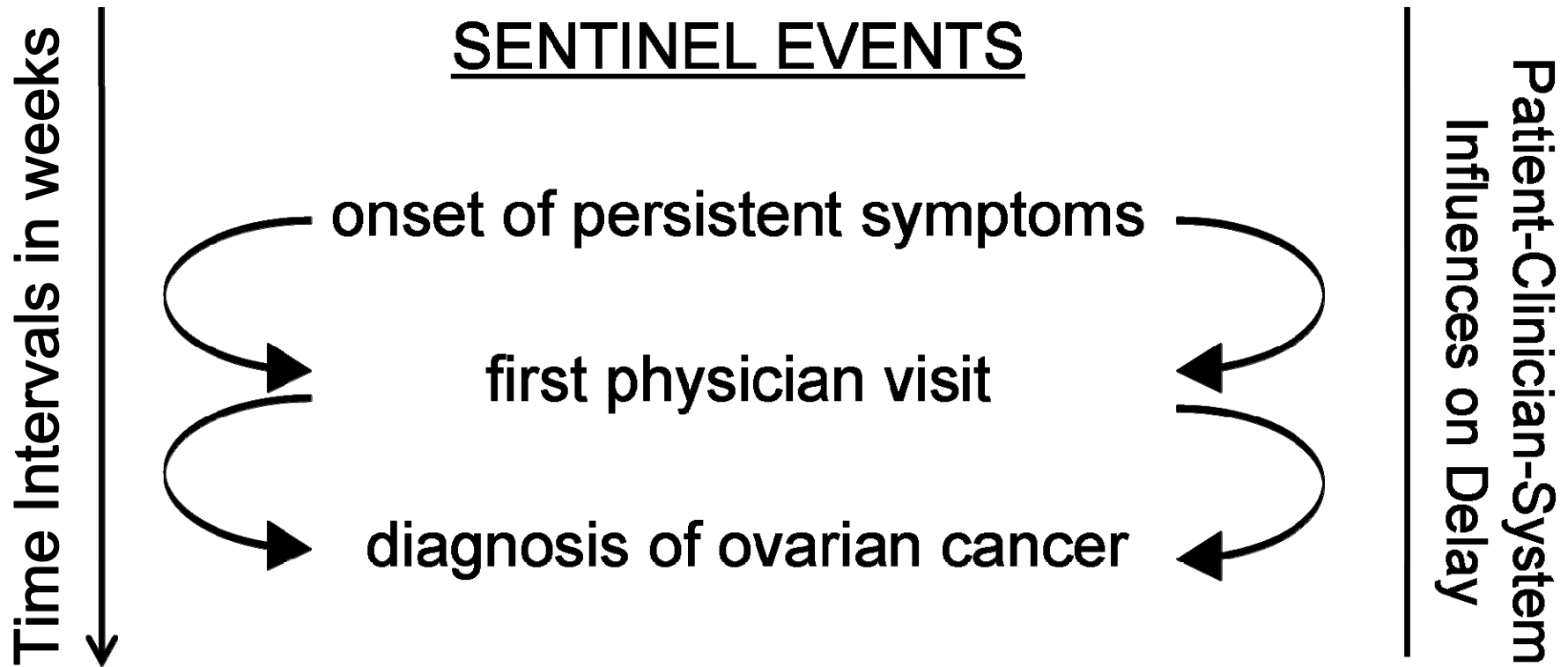
Collaborative Nursing Study

Pathway to diagnosis of ovarian cancer: an observational retrospective multicentered study

Primary Objectives

- Describe the frequency and duration of symptoms in the 12 months preceding the diagnosis of ovarian cancer (Goff symptoms survey)
- Describe time intervals of sentinel events
 - Onset of persistent symptoms
 - First physician visit
 - Diagnosis of ovarian cancer
- Describe the pathway to diagnosis according to Andersen's model of "total patient delay"

Pathway to diagnosis of ovarian cancer: an exploratory study





**Randomized phase II study of
carboplatin and paclitaxel +/-
cetuximab in advanced and/or
recurrent cervical cancer**

MITO CERV 2



Trial design

Aim: to assess the activity of a combination of cetuximab (weekly) with carboplatin + paclitaxel (every three weeks) comparing it to chemotherapy alone in terms of event-free survival (EFS)

RANDOM

Carbo AUC 5 + Paclitaxel 175 mg/mq q 21

Carbo AUC 5 + Paclitaxel 175 mg/mq + Cetuximab **400 mg/m²** one week before starting carboplatin and paclitaxel then **250 mg/m²** day 1, weekly

All drugs will be given for 3-6 cycles depending on clinical response, assessed every 3 cycles

Cetuximab will be continued until disease progression or unacceptable toxicity

Statistics



- Phase II, open-label, comparative, randomised, prospective, multicenter trial, comparing two treatment arms (1:1)
- Event free survival (EFS) primary endpoint, secondary endpoints toxicity, OS, skin toxicity and EGFR/KRAS expression correlations with cetuximab activity
- Exploratory study: one tailed, significance 20%, power 80%
- Hazard ratio of 0.70, 89 events are required
- # patients to enroll 108, accrual period 14 months

Thank you for your attention



<http://www.mito-group.it>

