A Multi-National, Randomized, Phase III, GCIG Intergroup Study Comparing Pegylated Liposomal Doxorubicin (CAELYX??) and Carboplatin vs. Paclitaxel and Carboplatin in Patients with Epithelial Ovarian Cancer in Late Relapse (>6 months)

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON30626

Source
ToetsingOnline

Brief title
CALYPSO STUDY

Condition

- Reproductive neoplasms male malignant and unspecified

Synonym
Epithelial Ovarian Cancer in Late Relapse

Research involving
Human

Sponsors and support

Primary sponsor: European Organisation for Research in Treatment of Cancer (EORTC)
Source(s) of monetary or material Support: EORTC,Schering-Plough

Intervention

Keyword: Late relapse threatment, ovarian cancer

Outcome measures

Primary outcome

Primary objective

• Progression-free survival (PFS) between both treatment groups

Secondary outcome

Secondary objectives

• Overall survival (OS)

• Toxicities

• Quality of life (QOL)

Study description

Background summary

Liposomal doxorubicin (Caelyx) is a new drug which has been shown to cause shrinkage or stabilization of the size of recurrent ovarian tumors in some patients and can be combined safely with carboplatin. Side effects observed with the combination of liposomal doxorubicin (Caelyx) and carboplatin are different from those observed with paclitaxel and carboplatin.

Study objective

The main purpose of this research study is to find out if treatment of late relapse with liposomal doxorubicin (Caelyx) combined with carboplatin will

control the tumor growth at least as well as standard treatment of paclitaxel and carboplatin. This study will look at the side effects of each combination. It is hoped that substituting paclitaxel with Caelyx in combination with carboplatin will improve the tolerance of the treatment program with at least the same efficacy and fewer side effects.

Study design

This is an open-label, multi-center, multi-national Intergroup, controlled, randomized Phase III trial comparing Caelyx / Carboplatin vs. Paclitaxel / Carboplatin in the treatment of patients with epithelial ovarian cancer in late relapse. The patients will be randomized to either of the following treatments:
1. STUDY GROUP: CAELYX-CARBOPLATIN
2. CONTROL GROUP: PACLITAXEL-CARBOPLATIN
A 3-week schedule defines a course of treatment.

Intervention

Starting dose of Caelyx - Carboplatin Caelyx 30 mg/m2 day 1 Carboplatin AUC 5 day 1 q 28 days / 6 courses or to progression Starting dose of Paclitaxel - Carboplatin Paclitaxel 175 mg/m2 day 1 Carboplatin AUC 5 day 1 q 21 days / 6 courses or to progression

Study burden and risks

Lowering of blood cell counts is a common side effect of liposomal doxorubicin (Caelyx) carboplatin and paclitaxel. Other common side effects that may occur are: numbness and tingling in the hands and feet that may lead to difficulty walking, buttoning clothes; hair loss; nausea; vomiting. Occasional side effects could be: allergic reactions; taste changes; alopecia; pain; asthenia; ulceration of the skin if the drug escapes from the vein; muscle and/or joint aches; skin irritation and tenderness at the injection site; allergic reactions with hives; wheezing and low blood pressure; sores in the mouth; tiredness; taste changes; nausea and vomiting; diarrhea; inflammation of the colon and intestine; abnormalities in heart rate, such as a slow regular pulse (a slow pulse is not harmful; however, if you should develop any other irregularities in heart rate during treatment, an electrocardiogram and other tests may be required); mouth sores; skin rashes on the soles of feet and palms of hands and along skin folds; blistering and ulceration may also occur but are rare; hair loss; asthenia, loss of appetite.

Contacts

Public

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients aged > 18 years
- Patients with a histological proven diagnosis of cancer of the ovary, the fallopian tube or extra-ovarian papillary serous tumors
- Patients with measurable disease (RECIST criteria) or CA 125 assessable disease (GCIG criteria) or with histological proven diagnosis of relapse
- Patients with disease in progression > 6 months after a first or second platinum-based line. Patients should have previously received a taxane derivative
- Patients with ECOG performance status < 2
- Patients with a life-expectancy of at least 12 weeks
- Adequate bone marrow, renal and hepatic function defined as
• WBC > 3.0 x 109/l or Neutrophils (*ANC) >= 1,5 × 109 /l
*Absolute Neutrophil Count
• Platelets >= 100 × 10 9/l
• Hemoglobin > 6 mmol/l (> 10,0 mg/dl)
• Bilirubin <= 2 × upper normal limit of normal range
• Estimated glomerular filtration rate >= 40 ml/min according to Cockroft-Gault formula

Exclusion criteria

- brain metastases
- heartdesease

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-06-2007
Enrollment:	140
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Caelyx
Generic name:	pegylated liposomal doxorubicin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Paraplatin
Generic name:	Carboplatin
Registration:	Yes - NL intended use
Product type:	Medicine

Brand name:	Taxol
Generic name:	Paclitaxel
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	09-05-2006
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	25-07-2006
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	27-03-2007
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	21-05-2007
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2004-004456-39-NL
CCMO	NL12184.041.06