A Phase 3 Randomized, Double-blind, Placebo-controlled, Multicenter Study of AMG 386 With Paclitaxel and Carboplatin as First-line Treatment of Subjects With FIGO Stage III-IV Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Cancers

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To estimate the treatment effect and safety of AMG 386 in combination with paclitaxel + carboplatin in subjects with FIGO Stage III-IV Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Cancers.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Ovarian and fallopian tube disorders
Study type	Interventional

Summary

ID

NL-OMON41365

Source
ToetsingOnline

Brief title
TRINOVA-3

Condition

- Ovarian and fallopian tube disorders

Synonym
Ovarium and Fallopian Tube cancer + Primary Peritoneal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Amgen
Source(s) of monetary or material Support: Amgen

Intervention

Keyword: AMG386, FIGO III-IV, First-line treatment, Ovarium/fallopian tube/primary peritoneal

Outcome measures

Primary outcome

Progression free survival

Secondary outcome

Overall survival

Study description

Background summary

In this study, the study medication AMG 386 is evaluated for the treatment of patients with FIGO Stage III-IV Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Cancers. AMG 386 is a man-made medication that is designed to stop the development of blood vessels in cancer tissues. Cancer tissues rely on the development of new blood vessels, a process called angiogenesis, to obtain a supply of oxygen and nutrients to grow. AMG 386 is considered experimental (or investigational). AMG 386 is not approved by any regulatory organization (such as the Food and Drug Administration, FDA) to treat any type of cancer. AMG 386 will be evaluated in this study in combination with paclitaxel and carboplatin.
About 1000 patients will participate in this study from regions including the Unites States and Europe. Amgen Inc. a for-profit drug company, is funding this clinical study.

Study objective

To estimate the treatment effect and safety of AMG 386 in combination with

paclitaxel + carboplatin in subjects with FIGO Stage III-IV Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Cancers.

Study design

This is a multicentre, randomized, phase 3 study. The study consists of 3 of parts. The first part is the screening. If the patient is eligible for the study, she will go into the treatment phase and this phase lasts until the patients had 18 months treatment during the maintenance phase.
After completion of the treatment, the patient will be followed by the study staff by telephone or at clinic visits approximately every 3 months for up to 6 years after the last subject started with the study.
Each subject participating in this clinical research study will receive 1 of the following treatments:
Arm A: AMG 386 with Paclitaxel and Carboplatin
Arm B: Placebo with Paclitaxel and Carboplatin

Intervention

Subjects will receive besided blinded AMG386 or placebo (QW, 18 weeks treatment phase and 18 months maintanance phase), paclitaxel (Q3W, 6 cycles) and carboplatin (Q3W, 6 cycles).

Study burden and risks

Risk:
Adverse effects of study medication AMG386. During the visits to the hospital the subjects will be monitored for adverse events

Burden:
Maximum study duration is about 102 months. The subject will visit the hospital every week. The duration of each visit will vary from 1 to 6 hours.

Contacts

Public
Amgen

Minervum 7061
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NL
Scientific
Amgen

Minervum 7061
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NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Female subjects 18 years of age or older with FIGO Stages III-IV epithelial ovarian, primary peritoneal or fallopian tube cancer with an indication for first-line treatment with paclitaxel and carboplatin x 6 cycles (subjects with pseudomyxoma, mesothelioma, adenocarcinoma with unknown primary tumour, carcinosarcoma, sarcoma, mucinous or neuroendocrine histology are excluded);Subjects with FIGO Stage IIIA or IIIB disease must have undergone PDS for ovarian, primary peritoneal or fallopian tube cancer within 12 weeks prior to randomization;Subjects with FIGO Stage IIIc or IV disease must either:;- undergo PDS for epithelial ovarian, primary peritoneal or fallopian tube cancer within 12 weeks prior to randomization;or;- plan to have IDS following 3 cycles of paclitaxel and carboplatin plus AMG 386 or AMG 386 placebo for biopsy proven epithelial ovarian, primary peritoneal or fallopian tube cancer;ECOG performance status os 0 or 1;Adequate bone marrow, renal and hepatic funtion

Exclusion criteria

Prior use of any anticancer therapy or experimental therapy for epithelial ovarian, primary peritoneal or fallopian tube cancers;Previous abdonimal and/or pelvic external beam radiotherapy;History of central nervous metastasis;History of arterial or venous thromboembolism within 12 months prior to randomization;Clinically significant cardiovascular disease within 12 months prior to randomization

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-04-2012
Enrollment:	8
Type:	Actual

Ethics review

Approved WMO Date:	12-12-2011
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	05-03-2012
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	11-05-2012
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	24-05-2012

Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	11-06-2012
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	14-06-2012
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	13-12-2012
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	19-12-2012
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	28-12-2012
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	29-01-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	11-02-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	08-03-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	02-04-2013

Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	01-05-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	18-09-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	24-09-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	24-03-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	12-06-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	26-06-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	15-07-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	12-09-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	24-09-2014

Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	29-07-2015
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	11-08-2015
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	10-03-2016
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	23-03-2016
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	EUCTR2011-001112-53-NL
ClinicalTrials.gov	NCT01493505
CCMO	NL38125.058.11