

# 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

Published: 12-12-2011

Last updated: 01-05-2024

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.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Ovarian and fallopian tube disorders
<b>Study type</b>	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 United 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 besides blinded AMG386 or placebo (QW, 18 weeks treatment phase and 18 months maintenance 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

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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 0 or 1;Adequate bone marrow, renal and hepatic function

### **Exclusion criteria**

Prior use of any anticancer therapy or experimental therapy for epithelial ovarian, primary peritoneal or fallopian tube cancers;Previous abdominal 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