# A randomized phase II study investigating the addition of the specific cox-2 inhibitor celecoxib to docetaxel plus carboplatin as first-line chemotherapy for stage IC-IV epithelial ovarian fallopian tube or primary peritoneal carcinomas

	Prospectively registered
No longer recruiting	☐ Protocol
Overall study status	Statistical analysis plan
Completed	Results
Condition category	Individual participant data
Cancer	Record updated in last year
	Completed  Condition category

# **Plain English summary of protocol**Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

EudraCT/CTIS number

IRAS number

# ClinicalTrials.gov number

# Secondary identifying numbers

**NTR471** 

# Study information

#### Scientific Title

## Acronym

Doca-Cel

# **Study objectives**

To evaluate the antitumoural efficacy of celecoxib in combination with docetaxel/carboplatin in terms of: response rate, progression-free survival.

The secondary objectives are:

- 1. To evaluate the safety and tolerability of this experimental treatment arm
- 2. To assess overall survival

# Ethics approval required

Old ethics approval format

## Ethics approval(s)

Received from the local medical ethics committee

# Study design

Multicentre, randomised, active controlled, parallel group trial

## Primary study design

Interventional

# Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

# Participant information sheet

## Health condition(s) or problem(s) studied

Epithelial ovarian cancer, fallopian tube cancer, primary peritoneal carcinomas

## **Interventions**

Arm 1 (control arm): docetaxel 75 mg/m2 plus Carboplatin AUC 5, both intravenous (iv) on day 1, every 3 weeks, for 6-9 cycles.

Arm 2: Docetaxel 75 mg/m2 plus Carboplatin AUC 5, both iv on day 1, every 3 weeks, for 6-9

cycles, together with celecoxib, 400 mg BID. Celecoxib will be continued for a maximum of 3 years or until progressive disease develops or until unacceptable toxicity occurs. In case docetaxel/carboplatin is permanently discontinued due to toxicity prior to course 4, celecoxib will be discontinued and patient goes off study.

# Intervention Type

Other

## **Phase**

Phase II

# Primary outcome measure

- 1. Response rate
- 2. Progression-free survival

# Secondary outcome measures

- 1. Safety
- 2. Overall survival
- 3. Tolerability

# Overall study start date

01/11/2002

## Completion date

01/12/2007

# **Eligibility**

## Key inclusion criteria

- 1. Histologically confirmed epithelial ovarian carcinoma, fallopian tube cancer or primary peritoneal cancer
- 2. Age >18 years
- 3. FIGO stages Ic-IV with or without successful cytoreductive surgery at staging laparotomy
- 4. Written informed consent
- 5. Can comply with follow-up requirements
- 6. The subject is willing to abstain from chronic use of all NSAIDs or COX-2 inhibitors. Chronic use of NSAIDs is defined as a frequency of 7 consecutive days (1 week) for >3 weeks per year or more than 21 days throughout the year.

# Participant type(s)

**Patient** 

## Age group

Adult

## Lower age limit

18 Years

#### Sex

Female

# Target number of participants

200

# Key exclusion criteria

- 1. ECOG performance status >2
- 2. Prior treatment with chemotherapy or radiotherapy
- 3. More than 6 weeks between initial laparotomy/surgery and planned commencement of chemotherapy
- 4. Patients with, pre-existing fluid retention such as pleural effusion, pericardial effusion and ascites are not excluded from the study, but should be monitored closely for any deterioration. Efforts should be made to determine by cytological analysis whether any significant pre-existing fluid collections are due to ovarian cancer, and subsequent drainage is recommended before initiating chemotherapy.
- 5. Inadequate bone marrow function defined as neutrophils <1.5 x  $10^9/l$  or platelets <100 x  $10^9/l$
- 6. Inadequate renal function defined by a creatinine clearance <40 ml/min, calculated by the Cockcroft-Gault Formula
- 7. Inadequate liver function as defined by bilirubin > upper limit of normal or AST/ALT > 1.5  $\times$  upper limit of normal or ALP > 2.5  $\times$  upper limit of normal
- 8. Concurrent severe and/or uncontrolled co-morbid medical condition (i.e. uncontrolled infection, hypertension, established ischaemic heart disease or cerebrovascular disease, congestive heart failure NYHA class II-IV, peripheral arterial disease)
- 9. Patients with mixed mesodermal tumours
- 10. Patients with borderline ovarian tumours or tumours termed 'possibly malignant'
- 11. Adenocarcinoma of unknown origin, if histologically shown to be mucin-secreting cancer or if considered possibly to have a non-gynecological origin
- 12. History of previous malignancy within the previous 5 years (except curatively treated carcinoma in situ of the uterine cervix, or basal cell carcinoma of the skin), or concurrent malignancy (e.g. co-existing endometrial cancer)
- 13. History of prior serious allergic reactions (e.g. anaphylactic shock)
- 14. Known hypersensitivity to sulphonamides
- 15. Chronic use of NSAIDs, COX-2 inhibitors or Aspirin
- 16. Symptomatic peripheral neuropathy >NCIC-CTC grade II
- 17. Active peptic ulcer or gastrointestinal bleeding
- 18. Inflammatory bowel disease, uncontrolled Cohn's disease or ulcerative colitis
- 19. Unresolved bowel obstruction or sub-acute obstruction, current history of chronic diarrhea
- 20. Pregnant or lactating women (or potentially fertile women not using adequate contraception)

#### Date of first enrolment

01/11/2002

#### Date of final enrolment

01/12/2007

# Locations

#### Countries of recruitment

Netherlands

# Study participating centre VU University Medical Center

Amsterdam Netherlands 1007 MB

# Sponsor information

# Organisation

VU University Medical Center (The Netherlands)

# Sponsor details

Van der Boechorststraat 7 Amsterdam Netherlands 1081 BT

# Sponsor type

Not defined

## **ROR**

https://ror.org/00q6h8f30

# Funder(s)

# Funder type

Hospital/treatment centre

#### Funder Name

VU University Medical Center (Netherlands)

## **Funder Name**

Sanofi-Aventis (France)

# **Results and Publications**

# Publication and dissemination plan

Not provided at time of registration

Intention to publish date
Individual participant data (IPD) sharing plan

**IPD sharing plan summary**Not provided at time of registration