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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

Submission date 27/01/2006	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 27/01/2006	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 03/07/2009	**Condition category** Cancer	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 x upper limit of normal or ALP >2.5 x 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
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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