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.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25042

Source
NTR

Brief title
Doca-Cel

Health condition

Epithelial ovarian cancer, ovarian fallopian tube or primary peritoneal carcinomas

Sponsors and support

Primary sponsor: VU medical center
Source(s) of monetary or material Support: VU Medical Center
Sanofi

Intervention

Outcome measures

Primary outcome

Response rate, progression-free survival.

Secondary outcome

Safety, overall survival, tolerability.

Study description

Background summary

N/A

Study objective

To evaluate the antitumoural efficacy of celecoxib in combination with docetaxel/carboplatin in terms of: response rate, progression-free survival. The secondary objectives are: To evaluate the safety and tolerability of this experimental treatment arm. To assess overall survival.

Study design

N/A

Intervention

Arm 1 (control arm):

Docetaxel 75 mg/m2 plus Carboplatin AUC 5, both i.v. on day 1, q 3 weeks, for 6-90 cycles.

Arm 2:

Docetaxel 75 mg/m2 plus Carboplatin AUC 5, both i.v. on day 1, q 3 weeks, for 6-9 cycles, together with celecoxib, 400 mg BID. Celecoxib will be continued for 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.

Contacts

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Eligibility criteria

Inclusion criteria

1. Histologically confirmed epithelial ovarian carcinoma, fallopian tube cancer or primary peritoneal cancer;

2. Age ¡Ý 18 year;

3. FIGO stages Ic-IV with or without successful cytorecductive surgery at staging laparotomy;

4. Written informed consent;

5. Can comply with follow-up requirements;

6. The subjects 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.

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 109/l or platelets <100 x 109/l;

6. Inadequate renal function defined by a creatinin 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).

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2002
Enrollment:	200
Type:	Actual

Ethics review

Positive opinion

Date:	26-10-2005
Application type:	First submission

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
NTR-new	NL431
NTR-old	NTR471
Other	: N/A
ISRCTN	ISRCTN30851756

Study results

Summary results
N/A