Effect of Celecoxib on reponse, progression-free and overall survival, when added to standaard first line chemotherapy in advanced ovarian cancer.

No registrations found.

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

Summary

ID

NL-OMON23637

Source
Nationaal Trial Register

Brief title
DocaCel

Health condition

Ovarian Cancer; chemotherapy; celecoxib; docetaxel; carboplatin; Cox-inhibitor; fallopian tube; primary peritoneal cancer; FIGO stage 2-4; cytoreductive surgery;

Sponsors and support

Primary sponsor: Sanofi-Aventis
Pfizer
Source(s) of monetary or material Support: Sanofi-Aventis
Pfizer

Intervention

Outcome measures

Primary outcome

The primary objectives of this randomized phase II study are:

- To evaluate the antitumoral efficacy of celecoxib in combination with docetaxel/carboplatin in
terms of :

a) Response rate (cCR, cPR)

b) Progression-free survival (PFS)

Secondary outcome

The secondary objectives of this randomized phase II study are:

- To evaluate the safety and tolerability of this experimental treatment arm.

- To assess overall survival

Study description

Background summary

Effect of Celecoxib on reponse, progression-free and overall survival, when added to standaard first line chemotherapy in advanced ovarian cancer.

Study objective

Primairy Objectives:

- To evaluate the antitumoral efficacy of celecoxib in combination with docetaxel/carboplatin in terms of:

a) response (cCR, cPR, NC, PD)

b) progression-free survival

Secundairy Objectives:
-To evaluate the safety and tolerability of this experimental treatment arm.

-To assess Overall Survival

Study design

Interim analysis after 2x75 pts for response

Intervention

Oral Celecoxib 2 x 400 mg during and for 32 yrs after primary chemotherapy.

Contacts

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Eligibility criteria

Inclusion criteria

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

2. Age > 18 year

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.

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, ischaemic heart disease, myocardial infarction within previous 6 months, congestive heart failure).

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-gynaecological 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. Chronic use of NSAIDs, COX-2 inhibitors or Aspirin.

15. Symptomatic peripheral neuropathy > NCIC-CTC grade II.

16. Active peptic ulcer or gastrointestinal bleeding.

17. Inflammatory bowel disease, uncontrolled Crohn’s disease or ulcerative colitis.

18. Unresolved bowel obstruction or sub-acute obstruction, current history of chronic diarrhea.

19. 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:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2002
Enrollment:	200
Type:	Actual

Ethics review

Positive opinion

Date:	13-10-2008
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	NL1431
NTR-old	NTR1491
Other	METC UMCG : 2002/241
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A