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.

Gepubliceerd: 26-10-2005 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25042

Bron
NTR

Verkorte titel
Doca-Cel

Aandoening

Epithelial ovarian cancer, ovarian fallopian tube or primary peritoneal carcinomas

Ondersteuning

Primaire sponsor: VU medical center
Overige ondersteuning: VU Medical Center

Sanofi

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Response rate, progression-free survival.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-11-2002
Aantal proefpersonen:	200
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	26-10-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL431
NTR-old	NTR471
Ander register	: N/A
ISRCTN	ISRCTN30851756

Resultaten

Samenvatting resultaten
N/A