Effects of budesonide on the toxicity of cabazitaxel in metastatic castrate-resistant prostate cancer.

Gepubliceerd: 20-07-2011 Laatst bijgewerkt: 15-05-2024

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Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27669

Bron
NTR

Verkorte titel
CABARESC

Aandoening

cabazitaxel; budesonide; diarrhea; prostate cancer
cabazitaxel; budesonide; diarree; prostaatkanker

Ondersteuning

Primaire sponsor: Dept. of Medical Oncology

Erasmus MC Rotterdam – Daniel den Hoed Cancer Center
Groene Hilledijk 301
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The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The effects of budesonide on the incidence of cabazitaxel induced diarrhea.

Toelichting onderzoek

Achtergrond van het onderzoek

Cabazitaxel is a new drug to be used for the treatment of metastatic castrate resistant prostate cancer after progression on docetaxel therapy. Unfortunately, a relatively high incidence of diarrhea (50%, mainly during the 1st two cycles, median onset after 7 days of therapy) is limiting its dose/use.

The aim of this study is to assess the prophylactic effect of budesonide on cabazitaxel induced diarrhea. The hypothesis is that the local anti-inflammatory effects of budesonide will have a favorable effect on the incidence of diarrhea in cabazitaxel treatment. In a previous pharmacokinetic safety study no clear interaction between cabazitaxel and budesonide was shown.

Doel van het onderzoek

The primary aim of this trial is to evaluate whether the addition of budesonide to cabazitaxel results in a lower proportion of patients with grade 2-4 diarrhea during the 1st and/or 2nd cycle. It is assumed that the incidence of grade 2-4 diarrhea in the control group will be 25%.

Onderzoeksopzet

3 weekly during 10 cycles of cabazitaxel of 3 weeks.

Onderzoeksproduct en/of interventie

All patients are treated with cabazitaxel chemotherapy. The intervention group will receive budesonide oral 9 mg a day from 2 days before the first chemotherapy cyclus untill 2 weeks after the second cycle. The control group will not receive budesonide.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Metastatic castrate resistant prostate cancer (mCRPC) patients with documented disease progression;

2. If measureable disease: documented disease progression as defined in RECIST criteria v 1.1;

3. If non-measurable disease: documented rising PSA levels (at least 2 consecutive rises in PSA over a reference value taken at least 1 week apart) or appearance of new lesions;

4. Previous treatment with a docetaxel-containing regimen;

5. Age ≥ 18 years;

6. WHO performance status ≥ 1 (see appendix B);

7. Adequate renal and hepatic functions defined as (serum creatinin <150µmol/l (<1.7mg/dl), total bilirubin < 1.0 xULN; alanine aminotransferase (ALAT) and aspartate aminotransferase (ASAT) <1.5x ULN, in case of liver metastasis < 5 ULN; alkaline phosphatase (AF) < 5x ULN) In case of bone metastasis, AF < 10x ULN is accepted;

8. Adequate hematological blood counts defined as (absolute neutrophil count (ANC) > 1.5 x 109/L and platelets > 100 x 109/L);

9. Castration, either surgically or by continued LHRH agonist therapy;

10. Written informed consent according to ICH-GCP.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Impossibility or unwillingness to take oral drugs;

2. Serious illness or medical unstable condition requiring treatment, symptomatic CNS-metastases or history of psychiatric disorder that would prohibit the understanding and giving of informed consent;

3. Use of medications or dietary supplements known to induce or inhibit CYP3A (see section 5.11);

4. Use of hormonal agents other than Gn-RH agonists;

5. Chemotherapy within the last 4 weeks before randomization;

6. Radiotherapy within the last 4 weeks before randomization;

7. Known hypersensitiveness to corticosteroids;

8. Systemic or local bacterial, viral, fungal - or yeast infection;

9. Hepatic impairment (Child-Pugh score B-C);

10. Portal hypertension (grade 1-4 CTC-NCI criteria);

11. Ulcerative colitis, Crohn’s disease or celiac disease;

12. Simultaneous yellow fever vaccine.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	15-09-2011
Aantal proefpersonen:	250
Type:	Werkelijke startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41486
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2849
NTR-old	NTR2991
CCMO	NL37676.078.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON41486

Resultaten

Samenvatting resultaten

Nieuweboer et al. Effects of budesonide on cabazitaxel pharmacokinetics and cabazitaxel-induced diarrhea: A randomized open-label multicenter phase II study. Clin Cancer Res. 2016 Oct 4 [Epub ahead of print]