Studying the influence of budesonide on the exposure of cabazitaxel (Jevtana®) in patients with prostate cancer.

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21762

Source
NTR

Brief title
N/A

Health condition

prostate cancer
cabazitaxel
budesonide

Sponsors and support

Primary sponsor: Erasmus Medical Center, Daniel den Hoed Cancer Center
Source(s) of monetary or material Support: Sanofi-Aventis

Intervention

Outcome measures

Primary outcome

Evaluation of the interaction of budesonide on the plasma exposure of cabazitaxel.

Secondary outcome

Assesment of safety of concomitantly administrating cabazitaxel and budesonide in terms of potential side effects

Study description

Background summary

The aim of this study is to study a potential pharmacological interaction between budesonide and cabazitaxel to ensure the safety of concomitantly administrating these 2 agents.

Study objective

Budesonide does not alter the exposure of cabazitaxel in castrate resistant prostate cancer patients.

Study design

During two courses of cabazitaxel 13 blood samples for pharmacokinetic analysis are drawn to asses the effect of budesonide administration on cabazitaxel plasma exposure.

Intervention

Administration of budesonide during 12 days to asses a possible interaction between cabazitaxel and budesonide. Budesonide will be administered orally 3 times a day 3 mg through entocort capsules. The control group will only receive cabazitaxel.

Contacts

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Eligibility criteria

Inclusion criteria

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

A. If measureable: (RECIST v 1.1) progression;

B. If non-measurable: 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.

2. Previous treatment with a docetaxel-containing regimen;

3. Age ¡Ý 18 years;

4. WHO performance ¡Ý 1;

5. Adequate renal and hepatic functions (serum creatinin < 1.25x upper limit of normal (ULN), total bilirubin < 1.25xULN; alanine aminotransferase (ALAT) and aspartate aminotransferase (ASAT) < 2.5x ULN, in case of liver metastasis < 5 ULN; alkaline phosphatase (AF) < 5xULN);

6. Adequate hematological blood counts (absolute neutrophil count (ANC) ¡Ý 1.5 x 109/L, platelets ¡Ý 100 x 1012/L);

7. Written informed consent;

8. No chemotherapy within the last 4 weeks before start;

9. No radiotherapy within the last 4 weeks before start;

10. Castration, either surgically or by continued LHRH agonist therapy.

Exclusion criteria

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;

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

5. Hypersensitiveness to corticosteroids;

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

7. Liver cirrhosis;

8. Portal hypertension.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-04-2011
Enrollment:	18
Type:	Actual

Ethics review

Not applicable

Application type:	Not applicable

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	NL2703
NTR-old	NTR2840
Other	METC Erasmus Medical Center : 11-091
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
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]