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

No registrations found.

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

Summary

ID

NL-OMON27669

Source
Nationaal Trial Register

Brief title
CABARESC

Health condition

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

Sponsors and support

Primary sponsor: Dept. of Medical Oncology

Erasmus MC Rotterdam – Daniel den Hoed Cancer Center
Groene Hilledijk 301
3075 EA Rotterdam
The Netherlands

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. The effects of budesonide on other side effects of cabazitaxel (e.g. myelotoxicity);

2. Pharmacogenetics of cabazitaxel.

Study description

Background summary

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.

Study objective

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%.

Study design

3 weekly during 10 cycles of cabazitaxel of 3 weeks.

Intervention

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.

Contacts

Public
Erasmus MC Rotterdam – Daniel den Hoed Cancer Center
Department of Medical Oncology
 Room G4-80
Ron H.J. Mathijssen
Groene Hilledijk 301
Rotterdam 3075 EA
The Netherlands
+31 (0)10 7041338, buzzer 229
Scientific
Erasmus MC Rotterdam – Daniel den Hoed Cancer Center
Department of Medical Oncology
 Room G4-80
Ron H.J. Mathijssen
Groene Hilledijk 301
Rotterdam 3075 EA
The Netherlands
+31 (0)10 7041338, buzzer 229

Eligibility criteria

Inclusion criteria

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.

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 (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.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-09-2011
Enrollment:	250
Type:	Actual

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 41486
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

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]