Studying the influence of prednisone on docetaxel exposure.

No registrations found.

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

Summary

ID

NL-OMON22101

Source
NTR

Brief title
Doc-Pred

Health condition

patients with metastatic castration-resistant and hormone-sensitive prostate cancer

Sponsors and support

Primary sponsor: Erasmus Medical Center
Source(s) of monetary or material Support: Erasmus Medical Center

Intervention

Outcome measures

Primary outcome

To determine the influence of prednisone use on the pharmacokinetics (primary parameter AUC) of docetaxel, compared to docetaxel alone, in mCRPC and mHSPC patients.

Secondary outcome

To evaluate the incidence and severity of side-effects of treatment with docetaxel in absence and presence of prednisone.
 Other pharmacokinetic outcomes (i.e. clearance, maximum concentration (Cmax))

Study description

Background summary

In this study we try to determine the influence of prednisone on the exposure of docetaxel vs docetaxel alone in men with metastatic castration-resistant or hormone-sensitive prostate cancer.

Study objective

To determine the influence of prednisone on docetaxel pharmacokinetics compared to docetaxel alone

Study design

During cycle 3 and cycle 6 of docetaxel treatment

Intervention

docetaxel vs docetaxel and prednisone

Contacts

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Eligibility criteria

Inclusion criteria

1.Histologicallly or cytologically confirmed adenocarcinoma of the prostate without neuro-endocrine differentitation or small cell features.

2. Continued androgen deprivation therapy either by gonadotropin releasing hormone (GnRH) analogues or orchiedectomy

3. Age ≥18 years

4. Metastatic disease progression

5. ECOG performance status 0-1

6. Written informed consent according to ICH-GCP

Exclusion criteria

1. Impossibility or unwillingness to take oral drugs

2. Serious concurrent illness or medical unstable condition requiring treatment

3. Symptomatic CNS metastases or history of psychiatric disorder that would prohibit the understanding and giving of informed consent

4. Known hypersensitivity to studiemedication

5. Use of medication or dietary supplements known to induce CYP3A

6. Any active systemic or local bacterial, viral, fungal - or yeast infection.

7. Abnormal renal function defined as (within 21 days before randomization): Serum creatinin > 1.5 x upper limit of normal (ULN). If creatinine 1.0 - 1.5 x ULN, creatinine clearance will be calculated according to CKD-EPI formula and patients with creatinine clearance <60 mL/min will be excluded.

8. Abnormal liver functions consisting of any of the following (within 21 days before randomization):

o Total bilirubin ≥ 1 x ULN (except for patients with documented Gilbert’s disease)

o alanine aminotransferase (ALAT) and aspartate aminotransferase (ASAT) ≥ 2.5 x ULN. (in case of liver metastases >5 x ULN)

o Alkaline phosphatase (AF) > 5 x ULN (in case of bone metastases > 10 x ULN)

9. Abnormal hematological blood counts consisting of any of the following (within 21 days before randomization):

o Absolute neutrophil count ≤ 1.5 x 109/L

o Platelets ≤ 100 x 109/L

10. Geographical, psychological or other non-medical conditions interfering with follow-up

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):	01-09-2016
Enrollment:	18
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	02-09-2016
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	NL5857
NTR-old	NTR6037
Other	METC Erasmus MC : MEC 16-365

Study results

Summary results
http://dx.doi.org/10.1111/bcp.13889