Pharmacokinetic study of enzalutamide and cabazitaxel combination therapy

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

Samenvatting

ID

NL-OMON28269

Bron
NTR

Verkorte titel
Cabenza-study

Aandoening

Metastatic castrate-resistant prostate cancer (mCRPC)

Ondersteuning

Primaire sponsor: Erasmus University Medical Center, Cancer Institute, Rotterdam, The Netherlands
Overige ondersteuning: Astellas Pharma BV

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To determine the influence of enzalutamide on cabazitaxel AUC compared to cabazitaxel

alone in mCRPC patients.

Toelichting onderzoek

Achtergrond van het onderzoek

Since cabazitaxel will increasingly substitute docetaxel in the setting of mCRPC , it is important to investigate whether cabazitaxel PK is significantly and clinically relevantly influenced by enzalutamide treatment, especially after more than 3 weeks of concomitant use. Cabazitaxel is also extensively metabolized by CYP3A4 and it is expected that this drug is prone to drug-drug interactions with CYP3A inducing co-medication (like enzalutamide). In this study we therefore investigate the pharmacokinetics (PK) and safety of cabazitaxel concomitantly used with enzalutamide in men with mCRPC.

Doel van het onderzoek

Since cabazitaxel will increasingly substitute docetaxel in the setting of mCRPC , it is important to investigate whether cabazitaxel PK is significantly and clinically relevantly influenced by enzalutamide treatment, especially after more than 3 weeks of concomitant use. Cabazitaxel is also extensively metabolized by CYP3A4 and it is expected that this drug is prone to drug-drug interactions with CYP3A inducing co-medication (like enzalutamide). In this study we therefore investigate the pharmacokinetics (PK) and safety of cabazitaxel concomitantly used with enzalutamide in men with mCRPC.

Onderzoeksopzet

n.a.

Onderzoeksproduct en/of interventie

Cabazitaxel will be used as standard of care treatment. Enzalutamide is also registered for treatment of mCRPC, but in this study it will be administered solely for investigational purpose.

Contactpersonen

Publiek

Afdeling Medische Oncologie

Ron
Mathijssen

Wetenschappelijk

Afdeling Medische Oncologie

Ron
Mathijssen

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age: >=18 years

2. Histological or cytological confirmed diagnosis of mCRPC

3. ECOG Performance Status ¡Ü 1

4. Written informed consent according to ICH-GCP prior to screening evaluations

5. Patients who are, as per local protocol, eligible for treatment with standard of care cabazitaxel

6. Adequate organ function as defined by:

a. Total bilirubin ¡Ü 1.5 x ULN (except in case of documented Gilbert¡¯s disease)

b. ASAT ¡Ü 2.5 x ULN (or ¡Ü 5 x ULN if liver metastases are present)

c. ALAT ¡Ü 2.5 x ULN (or ¡Ü 5 x ULN if liver metastases are present)

d. Serum creatinin ¡Ü 1.5 x ULN

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Evidence of central nervous system disease

2. History of seizure or any condition predisposing to seizure

3. Use of concomitant medication predisposing to seizure

4. Use of (over the counter) medication or (herbal) supplements which can interact with either cabazitaxel or enzalutamide, e.g. by induction or inhibition of CYP3A4, CYP2C9 and CYP2C19

5. Unable or unwilling to abstain from grapefruit, grapefruit juice, herbal dietary supplements, and herbal tea during the study

6. Previous use of enzalutamide during the last 6 weeks prior to cabazitaxel treatment

7. Contraindications for use of enzalutamide

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	08-04-2015
Aantal proefpersonen:	14
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	09-04-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41753
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5018
NTR-old	NTR5164
CCMO	NL51749.078.14
OMON	NL-OMON41753

Resultaten

Samenvatting resultaten
n.a.