Study on the pharmacokinetic interaction between cabazitaxel and darolutamide in metastatic castration-resistant prostate cancer (mCRPC) patients.

Gepubliceerd: 12-05-2020 Laatst bijgewerkt: 15-05-2024

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

Samenvatting

ID

NL-OMON28448

Bron
NTR

Verkorte titel
CABADARO

Aandoening

metastatic castration-resistant prostate cancer

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: Bayer BV

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To determine the influence of darolutamide on the pharmacokinetics of cabazitaxel compared to cabazitaxel alone in mCRPC patients.

Toelichting onderzoek

Achtergrond van het onderzoek

Darolutamide (Nubeqa) is a novel androgen receptor antagonist drug for the treatment of non-metastatic castration resistant prostate cancer (CRPC), approved by the FDA and EMA. It does not inhibit major CYP enzymes or major transporters at clinically relevant concentrations, so it is thought to be less sensitive for drug-drug interactions (DDIs), compared to other agents. Several clinical studies investigating the efficacy of combining hormonal therapy, like androgen receptor antagonists, with chemotherapy in metastatic CRPC patients are ongoing and the first data are promising. However, due to DDIs between these agents, which likely affect the anti-tumor activity of the treatment, there is a need for testing new, potentially more effective chemo-hormonal combination regimens. In this study we will determine the influence of darolutamide on the pharmacokinetics of cabazitaxel compared to cabazitaxel alone in mCRPC patients.

Doel van het onderzoek

Darolutamide (Nubeqa) is a novel androgen receptor antagonist drug for the treatment of non-metastatic castration resistant prostate cancer (CRPC), approved by the FDA and EMA. It does not inhibit major CYP enzymes or major transporters at clinically relevant concentrations, so it is thought to be less sensitive for drug-drug interactions (DDIs), compared to other agents.

Onderzoeksopzet

2022

Onderzoeksproduct en/of interventie

Darolutamide 600mg b.i.d. for 12 weeks

Contactpersonen

Publiek

Erasmus Medisch Centrum
SAJ Buck

0107040704

Wetenschappelijk

Erasmus Medisch Centrum
SAJ Buck

0107040704

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age ≥ 18 years;
2. Patients with a confirmed diagnosis of mCRPC with an indication for cabazitaxel treatment at the standard dose of 20 mg/m2.
3. WHO performance ≤ 1
4. Able and willing to sign the Informed Consent Form prior to screening evaluations
5. Adequate baseline patient characteristics (complete blood count, serum biochemistry which involves sodium, potassium, creatinine, calculation of creatinine clearance, AST, ALT, gamma glutamyltranspeptidase, lactate dehydrogenase, ALP, Total bilirubin, Albumin, glucose)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Use of (over the counter) medication or (herbal) supplements which can interact with either cabazitaxel or darolutamide, e.g. by induction or inhibition of CYP3A4 or P-gp. Dexamethasone and prednisone are allowed.
2. Patients with known impaired drug absorption (e.g. gastrectomy and achlorhydria)
3. Known serious illness or medical unstable conditions that could interfere with this study requiring treatment (e.g. HIV, hepatitis, Varicella zoster or herpes zoster, organ transplants, kidney failure (GFR<60), serious liver disease (e.g. severe cirrhosis), cardiac and respiratory diseases)
4. Treatment with abiraterone, enzalutamide, apalutamide or darolutamide six weeks prior to day 1 of the study.

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:	01-09-2020
Aantal proefpersonen:	17
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	12-05-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50053
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8611
CCMO	NL73182.056.20
OMON	NL-OMON50053

Resultaten