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

No registrations found.

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

Summary

ID

NL-OMON28448

Source
NTR

Brief title
CABADARO

Health condition

metastatic castration-resistant prostate cancer

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: Bayer BV

Intervention

Outcome measures

Primary outcome

To determine the influence of darolutamide on the pharmacokinetics of cabazitaxel compared

to cabazitaxel alone in mCRPC patients.

Secondary outcome

1. To evaluate the efficacy of cabazitaxel and darolutamide combination therapy, by means of PSA response, compared to baseline.
2. To study the pharmacokinetic profile of darolutamide.
3. To evaluate the safety of cabazitaxel and darolutamide combination therapy.

Study description

Background summary

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.

Study objective

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.

Study design

2022

Intervention

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

Contacts

Public
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SAJ Buck

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Scientific
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Eligibility criteria

Inclusion criteria

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)

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2020
Enrollment:	17
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	12-05-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50053
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results