Probing intercellular heterogeneity in circulating tumor cells of de novo metastatic hormone sensitive prostate cancer patients

Gepubliceerd: 23-04-2020 Laatst bijgewerkt: 18-08-2022

We hypothesize that an improved understanding of the cellular heterogeneity, both between patients and within a single patient, will aid in developing improved individualized treatment strategies.

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25327

Bron
Nationaal Trial Register

Verkorte titel
PICTURES

Aandoening

Prostate cancer, Metastatic hormone sensitive prostate cancer, mHSPC

Ondersteuning

Primaire sponsor: Erasmus Medical Center
Overige ondersteuning: NWO

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The percentage of patients from who 30 single viable CTCs can be isolated from the DLA product.

Toelichting onderzoek

Achtergrond van het onderzoek

The number of treatment options for patients with high-risk metastatic Hormone Sensitive Prostate Cancer (mHSPC) are rapidly expanding. Both chemotherapy and intensified anti-hormonal treatments deliver a significant improvement in overall survival. However, we are currently unable to predict which therapies are most effective in individual patients and the scarce randomized trial data comparing the 2 modalities fail to identify a clear preference. Thus, developing predictive biomarkers may provide an improved scientific basis to further improve the treatment of mHSPC patients. We will study a novel single cell phenotyping platform that enables the “ex vivo” testing of heterogeneity in drug responsiveness on individual tumor cells. We aim to correlate the results of the “ex vivo” single cell drug responsiveness testing to the clinical outcome in patients and to generate hypotheses on how and whether this novel technology could help to stratify patients with mHSPC for treatment allocation.

Doel van het onderzoek

We hypothesize that an improved understanding of the cellular heterogeneity, both between patients and within a single patient, will aid in developing improved individualized treatment strategies.

Onderzoeksopzet

- Baseline: -28 days till -1 day
- DLA
- After 6 months of treatment
- At progression of disease
- Death

Onderzoeksproduct en/of interventie

From all patients, blood will be drawn to screen for eligibility, including a CellSave tube for circulating tumorcells count and circulating tumor DNA, tubes for liver, renal and bone marrow function. If eligible, patients will undergo a diagnostic leukapheresis (DLA) procedure.

Contactpersonen

Publiek

Erasmus MC
Khrystany Isebia

0107044375

Wetenschappelijk

Erasmus MC
Khrystany Isebia

0107044375

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• De novo mHSPC patient, no prior treatment for prostate cancer, including local treatments and ADT
• Intention to start treatment with ADT + docetaxel or ADT + Second Generation Androgen Receptor Targeted therapy
• Age ≥18 years
• WHO performance status ≤2.
• ≥ 2 adequate peripheral veins as access point for leukapheresis.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Known hypersensitivity to the anticoagulant used for apheresis
• Inadequate cardiac function or severe cardiovascular comorbidity
- Heart failure NYHA class III/IV
• Hemoglobin level < 6.0 mmol/L
• Coagulation disorders as defined by one of the following:
- Coagulation disorder in medical history
- Platelet count < 40 x 109/L;
Patients without anticoagulant therapy which affects PT or APTT, when:

- PT > 1.5 x ULN or PT-INR > 1.5 x ULN
- APTT > 1.5 x ULN
Patients with anticoagulant therapy which affects PT or APTT, when:
- PT or APTT > 1.5 x the upper limit of the desired therapeutic window
- Total bilirubin > 2.5 x ULN
• Known chronic viral infections
• Second active malignancy

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-08-2020
Aantal proefpersonen:	134
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8549
Ander register	METC Erasmus MC : MEC-2020-0422 / NL73860.078.20

Resultaten