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

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25327

Source
Nationaal Trial Register

Brief title
PICTURES

Health condition

Prostate cancer, Metastatic hormone sensitive prostate cancer, mHSPC

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

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

product.

Secondary outcome

- The number of CTC in mHSPC patients obtained in peripheral blood and obtained by DLA
- The correlation between the number of CTC at baseline and after six months of treatment (defined as 6 months from start treatment for mHSPC) to clinical outcome (defined as time to start mCRPC treatment, time to first line therapy for CRPC, time to mCPRC as defined by PCWG3(19) and overall survival
- The level of PSA secretion and cell stress factors on single CTCs after drug exposure
- The percentage of patients from whom chromosomal profiles of single CTCs can be successfully generated
- The levels of ctDNA in mHSPC patients obtained in peripheral blood at baseline and after six months.

Exploratory:
- The intra-patient and inter-patient heterogeneity in genotype and phenotype of single CTCs
- The correlation between genotypic and phenotypic characterization of single CTCs
- The correlation between genomic heterogeneity and phenotypic heterogeneity of individual cancer cells in poor and well
responding mHSPC patients.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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.

Contacts

Public
Erasmus MC
Khrystany Isebia

0107044375
Scientific
Erasmus MC
Khrystany Isebia

0107044375

Eligibility criteria

Inclusion criteria

• 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.

Exclusion criteria

• 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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2020
Enrollment:	134
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable
Application type: Not applicable

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	NL8549
Other	METC Erasmus MC : MEC-2020-0422 / NL73860.078.20

Study results