A Prospective Observational Study of Treatment Options in Men with metastatic hormone sensitive prostate cancer (mHSPC)

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24642

Source
NTR

Brief title
Triple AiM1

Health condition

Newly diagnosed metastatic hormone sensitive prostate cancer

Sponsors and support

Primary sponsor: Janssen-Cilag B.V.
Source(s) of monetary or material Support: Janssen-Cilag B.V.

Intervention

Outcome measures

Primary outcome

1) A comprehensive selection of PROM questionnaires are collected at pre-defined time

points, enables comparison of health-related Quality-of-Life.
2) Comparison of clinical effectiveness between treatments.
3) Description of medical resource utilization and health economics.
4) Description of trends and variations in outcomes, diagnostic methods and treatment patterns for newly diagnosed mHSPC over time

Secondary outcome

Overall survival, progression-free survival, duration of treatments, changes to treatment, reasons for initiation/alteration/termination of anti-cancer treatment

Study description

Background summary

The objective of this study is to document the treatment patterns and outcomes, characteristics and management of patients with newly diagnosed mHSPC in routine clinical practice, independent of treatment used.

Study objective

This study is designed to generate data for informative purposes and as a resource for future analyses. Thus, the results will be presented descriptively, and no formal hypotheses will be pre-specified.

Study design

Patients will be followed 2 years from inclusion

Intervention

Not applicable

Contacts

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Scientific

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Eligibility criteria

Inclusion criteria

Male, 18 years or older aged
Must have a confirmed newly diagnosis of metastatic hormone sensitive prostate cancer.
Must sign a participation agreement/ICF allowing data collection and source data verification in accordance with local requirements

Exclusion criteria

Currently enrolled in an investigational interventional study
Currently enrolled in an observational study sponsored or managed by a Janssen company
Patients with insufficient understanding of the Dutch language or cognitive impairment that impede proper answering of the questionnaires

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-05-2020

Enrollment:	450
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
Not applicable

Ethics review

Positive opinion

Date:	07-09-2021
Application type:	First submission

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	NL9719
Other	Adviescommissie nWMO MEC-U/Twente : NWMO18.11.051

Study results