Patient Reported Outcomes in the CAstration-resistant Prostate cancer RegIstry

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON44771

Source
ToetsingOnline

Brief title
PRO-CAPRI

Condition

- Reproductive neoplasms male malignant and unspecified

Synonym
prostate cancer; prostate carcinoma; CRPC

Research involving
Human

Sponsors and support

Primary sponsor: institute for Medical Technology Assessment, Erasmus Universiteit Rotterdam
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Castration-resistant prostate cancer (CRPC), Health related quality of life (HRQOL), patient reported outcomes, resource use

Outcome measures

Primary outcome

Primary endpoint: to determine the HRQOL at baseline and changes over time

during CRPC treatment

a. generic HRQOL by EQ VAS score and EQ-5D index value

b. cancer specific HRQOL by EORTC QLQ-C30 score

c. prostate cancer specific HRQOL by EORTC QLQ-PR25 score

Secondary outcome

Secondary endpoint: to determine

a. indirect non-medical costs during CRPC treatment (productivity losses due to

absenteeism)

b. direct medical costs outside the hospital during CRPC treatment (medical

resource use outside the hospital and informal care)

c. self-reported pain by BPI-SF pain severity and interference

Study description

Background summary

The annual incidence of castration-resistant prostate cancer (CRPC) in the Netherlands is estimated at 2868 patients. After development of CRPC, survival with best supportive care is not expected to exceed 12 months. Cancer has a great impact on
health related quality of life (HRQOL). Fortunately, several new treatments for CRPC have been registered. These treatments have a palliative nature, comparable survival benefits and considerable costs. Especially when survival

benefits are comparable, patient reported outcomes are essential to optimize patient selection for treatment in the general medical oncology practice. Moreover, patient reported outcomes are essential for economic evaluations. This study will provide knowledge of HRQOL outcomes and indirect costs in the daily practice of CRPC treatment. These outcomes will help patients and clinicians in clinical decision making, to determine optimal treatment strategies and guide future development of guidelines, from both a clinical and economical perspective.

Study objective

The objectives are to determine generic, cancer-generic and prostate cancer-specific HRQOL and costs outside the hospital in CRPC patients during treatment (including best supportive care, docetaxel, cabazitaxel, abiraterone and enzalutamide) in daily practice.

Study design

PRO-CAPRI is a prospective, observational, multi-center, cohort side study of the CAstration-resistant Prostate cancer RegIstry (CAPRI), an observational study in the Netherlands. In September 2012, the observational CAPRI registry has been started. Clinical and economical outcomes are registered from 1500 CRPC patients, retrospectively included since 01-01-2010 in 20 hospitals from the Netherlands. The CAPRI and PRO-CAPRI outcomes will be combined for analysis.

Study burden and risks

Since the only intervention is a self-administered questionnaire, risks are negligible. The questionnaires take approximately 30 minutes to complete. Every three months the questionnaires will be repeated.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. CRPC, newly diagnosed, as defined by either the treating doctor/physician, or by the definition: prostate cancer that is progressing despite medical or surgical castration. OR
2. CRPC, progressive on docetaxel and starting the first post-docetaxel line of anti-cancer treatment

Exclusion criteria

unable to complete questionnaires

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-06-2013
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	09-07-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-01-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-07-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-10-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-12-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-12-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27164
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL44602.029.13
OMON	NL-OMON27164