

# The \*Utrecht Prostate Cohort for cancer treatment intervention studies and long term evaluation (UPC)\* study

Published: 19-12-2019

Last updated: 19-08-2024

To set up a cohort that will serve as a multi-trial platform and facilitate evaluation of new interventional treatment for prostate cancer.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Reproductive neoplasms male malignant and unspecified
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON50026

### Source

ToetsingOnline

### Brief title

UPC

### Condition

- Reproductive neoplasms male malignant and unspecified
- Genitourinary tract disorders NEC

### Synonym

Prostate cancer

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht

**Source(s) of monetary or material Support:** ZonMw;IMDI; Health Holland;stichting LSH-TKI

## Intervention

**Keyword:** cmRCT, Cohort, Patient-reported outcomes, Prostate cancer

## Outcome measures

### Primary outcome

Clinical parameters (e.g. co-morbidity, oncological history, symptoms, imaging, technical and treatment data), clinical endpoints (e.g. toxicity, and survival outcomes) and patient reported outcomes (e.g. QOL).

### Secondary outcome

NA

## Study description

### Background summary

Prostate cancer is the most common cancer in men worldwide. Survival rates are high due to the typical non-aggressive nature of disease and effective treatments. Radical treatments such as surgery and radiotherapy often cause toxicity and long term side effects. Based on current available literature, the choices for primary therapy for clinically localized prostate cancer has a negative impact on cancer-specific quality of life (QOL). New treatments are being developed. We aim to build a multidisciplinary prostate cancer cohort. The Trials within Cohorts (TwICs) design will be conducted and as a prospective registry for assessment of long-term safety, performance and effectiveness of innovative treatments of prostate cancer. These treatments can also be compared to other treatments in a randomized fashion.

### Study objective

To set up a cohort that will serve as a multi-trial platform and facilitate evaluation of new interventional treatment for prostate cancer.

### Study design

Observational, prospective cohort study, according to the \*cohort multiple Randomised Controlled Trial\* (cmRCT) design.

## Study burden and risks

No risk expected for patients participating in the study. The only burden for participants will be filling out the questionnaires, approximately 30 minutes each time.

## Contacts

### Public

Universitair Medisch Centrum Utrecht

Heidelberglaan 100  
Utrecht 3584 CX  
NL

### Scientific

Universitair Medisch Centrum Utrecht

Heidelberglaan 100  
Utrecht 3584 CX  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Age  $\geq$  18 years.
- Patients with non-metastasised prostate cancer, referred for radiation treatment to the Radiotherapy Department of the UMC Utrecht or for prostatectomy, watchful waiting or active surveillance to the Urology

Department of St. Antonius hospital or the Urology Department of the UMC Utrecht.

- Informed consent - at least - for use of routinely collected clinical data

## Exclusion criteria

- Mentally incompetent patients.
- Inability to understand the Dutch language.
- Radical treatment of prostate cancer.

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 05-02-2020

Enrollment: 5000

Type: Actual

### Medical products/devices used

Registration: No

## Ethics review

Approved WMO

Date: 19-12-2019

Application type: First submission

Review commission: METC NedMec

Approved WMO	
Date:	04-03-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	18-02-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	29-04-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

## 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
CCMO	NL70198.041.19