# HYpofractionated irradiation for PROstate cancer: a randomised multicentre phase III study

Submission date [X] Prospectively registered Recruitment status 22/11/2006 No longer recruiting [ ] Protocol [ ] Statistical analysis plan Registration date Overall study status 22/11/2006 Completed [X] Results Individual participant data **Last Edited** Condition category 14/02/2020 Cancer

## Plain English summary of protocol

Not provided at time of registration

# **Contact information**

# Type(s)

Scientific

#### Contact name

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# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

CKTO 2006-08

# Study information

#### Scientific Title

Hypofractionated irradiation for PROstate cancer: a randomised multicentre phase III study

#### Acronym

**HYPRO** 

### Study objectives

The hypofractionated regimen of 19 fractions will result in an increase of relapse-free survival by 10% with the same acute and late toxicity as the standard fractionation of 39 fractions.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Medical Ethics Committee of Erasmus MC, The Netherlands, 13/06/2006, ref: MEC-2006-045

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Hospital

# Study type(s)

Treatment

#### Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

# Health condition(s) or problem(s) studied

Prostate cancer

#### **Interventions**

Hypofractionation arm:

Total dose of 64.6 Gy in 19 fractions of 3.4 Gy, three times per week, in 7 weeks, using conformal External Beam Radiation Therapy (EBRT).

#### Reference arm:

78 Gy total dose consisting of 39 fractions of 2 Gy, five times per week, in 8 weeks, using conformal EBRT.

#### Intervention Type

Other

#### Phase

Phase III

#### Primary outcome measure

Five-year relapse-free survival after treatment. Relapse is defined as biochemical relapse, clinical relapse, loco-regional or distant relapse or start with hormonal therapy, whichever occurs first. Biochemical relapse will be defined in this study as PSA greater than the current nadir plus 2 mg /l, without backdating.

Other endpoints of this study will be:

- 1. The acute gastro-intestinal and genito-urinary toxicities by using the RTOG/EORTC Late Radiation Morbidity Scale questionnaire and scoring system.
- 2. The late gastro-intestinal and genito-urinary toxicities by using the RTOG/EORTC Late Radiation Morbidity Scale questionnaire and scoring system.

#### Secondary outcome measures

- 1. Quality of life by using the EORTC-PR25 prostate module
- 2. Erectile functioning by using the International Index of Erectile Function (IIEF)

#### Overall study start date

01/12/2006

#### Completion date

01/12/2011

# Eligibility

#### Key inclusion criteria

- 1. Histologically proven adenocarcinoma of the prostate
- 2. Intermediate or high risk prostate cancer:
- 2.1. Low risk: T1-2a and Prostate Specific Antigen [PSA] less than 10  $\mu$ g/L and Gleason score less than or equal to six
- 2.2. Intermediate risk: Not low risk or high risk
- 2.3. High risk: One or more of the following high risk factors: T3-4, PSA more than 20  $\mu$ g/L, Gleason score more than or equal to eight)
- 3. The administration of concomitant hormonal therapy is allowed
- 4. World Health Organisation (WHO) performance status zero to two
- 5. Written informed consent
- 6. Willing to fill out the quality of life questionnaires

#### Participant type(s)

Patient

#### Age group

Adult

#### Sex

Male

## Target number of participants

800

#### Key exclusion criteria

- 1. Pretreatment PSA more than or equal to 60 μg/l
- 2. Previous irradiation in the pelvic region or radical prostatectomy
- 3. Radiological evidence of pelvic nodal disease (computed tomography [CT] pelvis)
- 4. Presence of distant metastasis (bone scintigraphy)
- 5. Patients candidates for elective lymph node irradiation
- 6. Low-risk prostate cancer (T1-2a and PSA less than 10  $\mu$ g/L and Gleason score less than or equal to six)

#### Date of first enrolment

01/12/2006

#### Date of final enrolment

01/12/2011

# Locations

#### Countries of recruitment

Netherlands

## Study participating centre Erasmus Medical Center

Rotterdam Netherlands 3008 AE

# Sponsor information

#### Organisation

Erasmus Medical Center (The Netherlands)

#### Sponsor details

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#### Sponsor type

Hospital/treatment centre

#### **ROR**

https://ror.org/018906e22

# Funder(s)

## Funder type

Research organisation

#### Funder Name

KWF Kankerbestrijding

#### Alternative Name(s)

The Dutch Cancer Society, Koningin Wilhelmina Fonds, DCS, KWF

#### **Funding Body Type**

Private sector organisation

## **Funding Body Subtype**

Other non-profit organizations

#### Location

Netherlands

# **Results and Publications**

# Publication and dissemination plan

Not provided at time of registration

# Intention to publish date

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

# Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2015		Yes	No
Results article	results	01/08/2016		Yes	No
Results article	results	01/01/2020	14/02/2020	Yes	No