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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 µg/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 µg/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 µg/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)

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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