

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

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)

ROR

<https://ror.org/018906e22>

Funder(s)

Funder type

Research organisation

Funder Name

KWF Kankerbestrijding

Alternative Name(s)

Dutch Cancer Society, Dutch Cancer Society (KWF Kankerbestrijding), KWF, DCS

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

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