HYpofractionated irradiation for PROstate cancer
A randomized multicenter phase III study.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22744

Source
NTR

Brief title
HYPRO study

Health condition

Prostate cancer has become the most common non-skin malignancy in men in Western countries. Over recent years the number of diagnosed patients has increased dramatically because of routine prostate-specific antigen (PSA) testing. For a large proportion of prostate cancer patients, external-beam radiotherapy (EBRT) will be the treatment of choice.

Sponsors and support

Primary sponsor: Erasmus MC-Daniel den Hoed Cancer Center, Rotterdam, Netherlands Cancer Institute, Amsterdam
Source(s) of monetary or material Support: Dutch Cancer Society

Intervention

Outcome measures

Primary outcome

5-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:

The acute gastro-intestinal and genito-urinary toxicities by using the RTOG/EORTC questionnaire and scoring system.

The late gastro-intestinal and genito-urinary toxicities by using the RTOG/EORTC questionnaire and scoring system.

Secondary outcome

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

Study description

Background summary

In the last decade substantial improvements in the external-beam radiotherapy for prostate cancer have been made. Most attention has been focused on the introduction of new techniques and dose escalation has significantly increased treatment outcome. Less attention has been paid to fractionation. The disparity between ¦Á/¦Â = 4 Gy for late complications and the values for prostate tumors (¦Á/¦Â ¡Ü 2) raises the prospect that we might be able to further improve treatment outcome by treating prostate cancer with hypofractionation. Hypofractionated schedules for prostate cancer could lead to a high therapeutic gain as well as economic and logistic advantages. The study wants to demonstrate the superiority of the hypofractionated schedule with respect to the relapse rate. It will be a prospective, open, randomized phase III trial. Patients will be randomized to a total dose of 78 Gy in 39 daily fractions of 2 Gy, 5 times/week, in 8 weeks or to a total dose of 64.6 Gy in 19 fractions of 3.4 Gy, 3 times/week, in 7 weeks.
End-points will be the 5-year relapse-free survival after treatment and the acute and late gastro-intestinal and genito-urinary toxicity. Secondary end-points: quality of life.

Study objective

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.

Intervention

hypofractionation arm: total dose of 64.6 Gy in 19 fractions of 3.4 Gy, 3 times/week, in 7 weeks, using conformal EBRT
reference arm: 78 Gy total dose consisting of 39 fractions of 2 Gy, 5 times/week, in 8 weeks, using conformal EBRT

Contacts

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Eligibility criteria

Inclusion criteria

1. Histologically proven adenocarcinoma of
the prostate

2. Intermediate or high risk prostate cancer

(Low risk: T1-2a and PSA < 10 µg/L and

Gleason score
Intermediate risk: Not low risk or high risk

High risk: One or more of the following
high risk factors: T3-4, PSA > 20 µg/L, Gleason score >/= 8)

3. The administration of concomitant
hormonal therapy is allowed

4. WHO performance status 0-2

5. Written informed consent

6. Willing to fill out the quality of life
questionnaires.

Exclusion criteria

1. Pretreatment PSA >/= 60 µg/l

2. Previous irradiation in the pelvic region or radical prostatectomy

3. Radiological evidence of pelvic nodal
disease (CT pelvis)

4. Presence of distant metastasis (Bone
scintigraphy)

5. Patients candidates for elective
lymphnode irradiation

6. Low risk prostate cancer. (T1-2a and PSA < 10 µg/L and Gleason score

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2006
Enrollment:	800
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-08-2006
Application type:	First submission

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
NTR-new	NL748
NTR-old	NTR759
Other	: CKTO 2006-08
ISRCTN	ISRCTN85138529

Study results

Summary results

N/A