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

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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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22744

Bron
NTR

Verkorte titel
HYPRO study

Aandoening

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.

Ondersteuning

Primaire sponsor: Erasmus MC-Daniel den Hoed Cancer Center, Rotterdam, Netherlands Cancer Institute, Amsterdam
Overige ondersteuning: Dutch Cancer Society

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2006
Aantal proefpersonen:	800
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	30-08-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL748
NTR-old	NTR759
Ander register	: CKTO 2006-08
ISRCTN	ISRCTN85138529

Resultaten

Samenvatting resultaten

N/A