Stereotactic body radiotherapy for cT1c - cT3a prostate cancer with a low risk of nodal metastases (<= 20%, Roach index): a Novalis Circle Phase II prospective randomized Trial*

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Aim of this study is to investigate the tolerance and the outcome of extreme hypofractionated RT for prostate cancer by delivering a high dose using two alternative time schedules, a short and long treatment interval.

Ethical review	Approved WMO
Status	Completed
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON39654

Source
ToetsingOnline

Brief title
IMRT stereo prostate cancer

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
prostate cancer, prostate carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Hopitaux Universitaires de Geneve
Source(s) of monetary or material Support: Brainlab, AG, Feldkirchen, Germany,Cellex foundation Barcelona,Cellex foundation Barcelona;Brainlab

Intervention

Keyword: hypofractionation, prostate cancer, stereotactic radiotherapy, treatment interval

Outcome measures

Primary outcome

Treatment tolerance and outcome in patients with early stage prostate cancer.

Secondary outcome

Quality of life studies (QOQL, EORTC); local failure; Biochemical disease-free

survival (bDFS); Metastases-free survival; Disease-specific survival.

Study description

Background summary

Total dose and dose per fraction play an important role in the curative treatment with radiotherapy (RT) of prostate cancer. Conventionally fractionated (2 Gy/fraction) dose escalation above 74 Gy has shown to be beneficial for prostate cancer.
Prostate cancer cells seem less radiosensitive characterized by a low a/b ratio.Thus, large treatment fractions (hypofractionation) may increase the tumor cell killing effect while biologically protecting the surrounding late responding normal tissues.
Preliminary results from two pilot studies (one with 5-year median follow-up) on extreme hypofractionation (5 daily fractions of 6.7 and 7.25 Gy over 5 days, respectively) have been reported. Those patients were treated with stereotactic beam radiotherapy (SBRT) receiving an equivalent total dose to the tumor in 2 Gy fractions of 78 and 90 Gy, respectively with 5-year biochemical disease control rates above 90%.
Therefore, there is a need to test the effect on tolerance and outcome of large fractions delivered in short and long treatment intervals as it is proposed in the present study: i.e., 5 x 7.25 Gy in 9 days (every other day, qod) versus the same dose and fractionation but in 28 days (once-a-week). Extreme

hypofractionation for prostate cancer may not only be biologically sound (i.e., more cure with less side effects), but also economically advantageous. In fact, a drop from 40 or more treatments to only 5 sessions, as suggested above, may significantly reduce the cost of external beam RT. Furthermore, it will increase the availability of treatment slots in otherwise busy departments, and finally improve patient*s convenience.

Study objective

Aim of this study is to investigate the tolerance and the outcome of extreme hypofractionated RT for prostate cancer by delivering a high dose using two alternative time schedules, a short and long treatment interval.

Study design

Multicenter, prospective randomized clinical phase II study

Intervention

152 patients will be asked to participate. They will be randomized in two groups. The treatment will be delivered in a short and long treatment intervals i.e., 5 x 7.25 Gy in 9 days (every other day, qod) versus the same dose and fractionation but in 28 days (once-a-week). A total of 76 patients will have to be recruited in each treatment arm.

Study burden and risks

The technique of radiotherapy and the mentioned side-effects are comparable with the treatment as standard given. During an extra examination, post-treatment rectal effects will be assessed with a recto-sigmoidoscopy performed at 18 to 24 months after RT. The chance of perforation or side-effects of medication needed during scopy are small.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Age: adult
2. WHO performance status <= 2
3. Any patient where prophylactic lymph node irradiation is not required, i.e. risk of nodal microscopic involvement <= 20%
4. T-stage: cT1-cT3a
5. Previous TURP is allowed provided there is at least 8 weeks interval with radiotherapy
6. Combined hormonal treatment (Neoadjuvant-concomitant hormonal deprivation for 6 months) is mandatory if two or more of the following tumour characteristics are present: >=cT2c, Gleason 4+3, PSA >10 ng/ml, perineural invasion, and/or >1/3 of positive biopsies
7. Concomitant and adjuvant HT for 4 more months

Exclusion criteria

1. Inability to obtain a written informed consent
2. Patient preference to be treated with one rather than the other treatment arm.
3. WHO performance status > 2
4. cT3b,cT4
5. Gleason score >=8
6. Clinical N+ on metastases work-up or N+ risk >20%
7. Severe urinary obstructive symptoms (IPSS symptom index >19)
8. Previous TURP less than 8 weeks before radiotherapy
9. Previous prostate surgery other than TURP

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	18-09-2013
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	06-02-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
ClinicalTrials.gov	NCT01764646
CCMO	NL41814.029.12