

Which correction protocol gives the lowest cumulative rectal dose in prostate cancer patients who are treated with external beam radiotherapy? A phase II modelling study

Submission date 26/02/2007	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 26/02/2007	Overall study status Completed	☐ Protocol
Last Edited 22/09/2021	Condition category Cancer	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

MEC 06/268, NL865 (NTR879)

Study information

Scientific Title

Which correction protocol gives the lowest cumulative rectal dose in prostate cancer patients who are treated with external beam radiotherapy? A phase II modelling study

Study objectives

To reduce cumulative radiation dose in the rectum in prostate cancer patients who are treated with curative intent using external beam radiotherapy. We will investigate whether position correction based on implanted gold markers or re-planning based on sequential Computed Tomography (CT) scans (adaptive margin strategy) is required instead of standard position correction protocols based on bony anatomy. With this knowledge we intend to develop a new treatment protocol for patients with prostate cancer for our department.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the local medical ethics committee (Medische Etische Commissie Academisch Medisch Centrum) on the 19th December 2006 (ref: MEC 06/268).

Primary study design

Interventional

Study design

Prospective phase II modeling study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

External beam radiotherapy, prostatic neoplasms, rectal toxicity, position verification

Interventions

Before the start of the treatment four gold seeds will be implanted in the prostate of the patients. Treatment consists of external beam radiotherapy (77 - 78 Gy) with curative intent. During radiotherapy the prostate position will be measured daily using Portal Imaging (PI) of the gold seeds and bony anatomy and treatment position corrections will be performed using standard daily offline correction protocols for optimal prostate treatment.

In addition to the standard treatment, a CT scan will be performed every day during the first week and once a week thereafter. After the first week an Adaptive Margin Radiotherapy (AMRT) treatment plan will be made, considering both averaged prostate and rectum positions in the first five scans. The cumulative rectum dose will be computed for the original treatment plan, considering repositioning based on PI for bony anatomy and markers and considering the adaptive margin strategy.

Intervention Type

Other

Phase

Phase II

Primary outcome(s)

D30% rectal wall (the minimum dose in 30% of the rectal wall that receives the highest dose) from the cumulative dose-volume-histograms

Key secondary outcome(s)

1. D10% rectal wall, D50% rectal wall, D70% rectal wall
2. D mean anal canal
3. Crude cost analysis

Completion date

01/02/2008

Eligibility

Key inclusion criteria

1. Histologically proven localised (cT1-3) adenocarcinoma of the prostate
2. Primary treatment for the prostate cancer with more than 70 Gy radiotherapy with curative intent
3. World Health Organisation (WHO) performance status zero to two
4. The administration of concomitant hormonal therapy is allowed, however only if started more than six months before radiotherapy to limit the possibility of shrinkage of the prostate during the course of radiotherapy
5. Be able to lie in lithotomy position
6. Meet all Magnetic Resonance Imaging (MRI) safety criteria

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Male

Total final enrolment

20

Key exclusion criteria

1. No hip prosthesis
2. No involvement of pelvic lymph node assessed by CT scan or laparoscopic surgery
3. No evidence of distant metastases
4. No Transurethral Resection of the Prostate (TUR-P) in the last three months
5. No anorectal surgery in the past or other situations in which the anorectal anatomy is abnormal
6. No use of anticoagulation therapy (i.e. coumarins or heparins), however the use of anti-platelet therapy is allowed
7. No coagulation disorder

Date of first enrolment

01/02/2007

Date of final enrolment

01/02/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

Academisch Medisch Centrum

Amsterdam

Netherlands

1105 AZ

Sponsor information

Organisation

Academic Medical Centre (AMC) (The Netherlands)

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Academic Medical Centre (AMC) (The Netherlands)

Results and Publications

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		01/06/2011	22/09/2021	Yes	No