Magnesium oxide to reduce prostate motion.

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24191

Source
NTR

Brief title
Magnesium oxide to reduce prostate motion

Health condition

1. Prostate cancer;

2. radiotherapy.

(NLD: prostaatkanker, bestraling).

Sponsors and support

Primary sponsor: University Medical Center Utrecht, The Netherlands
Source(s) of monetary or material Support: University Medical Center Utrecht, The Netherlands

Intervention

Outcome measures

Primary outcome

The main study parameter is the movement of the prostate during a fraction of radiotherapy. The three fiducial markers are being imaged 5 times during one fraction. These 5 images can be used to derive the range of the intrafraction movement of the prostate.

Secondary outcome

Toxicity will be measured by the Common Toxicity Criteria (CTC) version 3.0 (Trotti). The physician in attendance will score the complaints before treatment and acute toxicity will be scored weekly during the treatment and four weeks after the treatment. All symptoms will be registered even if they occur only on one single occasion.

The Quality of Life (QoL) before treatment and after the treatment will be measured by RAND-36 (general health), EORTC QLQ-C30 (+3) (cancer specific) and the EORTC QLQ-PR25 (prostate specific) (Hornbrook, Aaronson, Borghede). The first QoL questionnaire will be hand over to the patient at the department and the second questionnaire will be sent to the patient.

The amount of gas will be counted by delineation of the gas pockets on the CT-scan and MR-scan before the treatment.

Study description

Background summary

Rationale:

Some institutes use magnesium oxide to reduce the movement of the prostate during radiotherapy treatment, however this treatment is not evidence based. The hypothesis is that magnesium oxide is effective in reducing the intrafraction motion of the prostate during radiotherapy treatment for prostate cancer.

Objective:

Main: reduced intrafraction motion.

Secondary:

1. changed toxicity;

2. change quality of life;

3. reduced gas inside the rectum.

Study design:

Double-blind placebo-controlled randomized intervention study.

Study population:

Prostate cancer patients who are being treated with external beam radiotherapy using fiducial marker-based position verification.

Intervention:

One group receives a capsule of 500mg magnesium oxide twice a day and the other group receives a placebo capsule twice a day during the radiotherapy treatment.

Main study parameters:

Reducing the intrafraction motion of the prostate with 30%.

Study objective

The hypothesis is that magnesium oxide is effective in reducing the intrafraction motion of the prostate during radiotherapy treatment for prostate cancer.

Study design

Before radiotherapy, during the 7 weeks radiotherapy treatment and 4 weeks after

radiotherapy.

Intervention

One group receives a capsule of 500mg magnesium oxide twice a day and the other group receives a placebo capsule twice a day during the radiotherapy treatment.

Contacts

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Eligibility criteria

Inclusion criteria

Prostate cancer patients scheduled for external beam radiotherapy using fiducial marker-based position verification.

Exclusion criteria

1. Patients with known severe constipation;

2. Patients who receive laxatives;

3. Patients with a history of abdominal surgery;

4. Patients with known abdominal diseases (M. Crohn, colitis ulcerosa, diverticulitis);

5. Patients with known severe renal failure;

6. Patients who receive tetracyclines, digoxine, iron or ciprofloxacine;

7. Patients with known kidney stones.

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2008
Enrollment:	184
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL1126
NTR-old	NTR1161
Other	N/A : 20599
ISRCTN	Wordt niet aangevraagd (NVT)

Study results

Summary results
N/A