# Double-blind placebo-controlled randomized study to determine the effectiveness of magnesium oxide to reduce the prostate motion.

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Primairy objective: Does the use of daily magnesium oxide reduce the prostate movements during a radiotherapy fraction? Secondary objectives: Does the use of magnesium oxide change the acute toxicity of the treatment? Does the use of magnesium oxide…

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Reproductive neoplasms male malignant and unspecified |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON31671

**Source**
ToetsingOnline

**Brief title**
Magnesium oxide to reduce prostate motion.

### Condition

- Reproductive neoplasms male malignant and unspecified

**Synonym**
prostate cancer, prostate carcinoma

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** intrafraction motion, magnesium oxide, prostate cancer, radiotherapy

## Outcome measures

### Primary outcome

The primary 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 position of the prostate.

### Secondary outcome

Toxicity will be measured by the Common Toxicity Criteria (CTC) version 3.0. 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.

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). The first QoL questionnaire will be hand over to the patient at the department and the second questionnaire will be sent to the patient 4 weeks after the treatment.

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

# Study description

### Background summary

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.

### Study objective

Primairy objective: Does the use of daily magnesium oxide reduce the prostate movements during a radiotherapy fraction?

Secondary objectives: Does the use of magnesium oxide change the acute toxicity of the treatment?
Does the use of magnesium oxide change the quality of life?
Does the use of magnesium oxide reduce the amount of gas inside the rectum?

### Study design

Double-blind placebo-controlled randomized intervention study

### Intervention

One group receives two capsules of 250mg magnesium oxide twice a day and the other group receives two placebo capsules twice a day during the radiotherapy treatment.

### Study burden and risks

Patients should take twice a day a capsule during the radiotherapy treatment and have to fill in a quality of life questionnaire before and after the radiotherapy treatment and.
The risk associated with the intake of magnesium oxide is physical discomfort consisting of diarrhoea.
Patient will undergo one venous puncture.

# 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

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

## Exclusion criteria

-Patients with known severe constipation
-Patients who receive laxatives
-Patients with a history of abdominal surgery
-Patients with known abdominal diseases (M. Crohn, colitis ulcerosa, diverticulitis )
-Patients with known severe renal failure or creatinine clearance of < 50 ml/min/1.73 m2
-Patients who receive tetracyclines, digoxine, iron or ciprofloxacine and the intake of this

medication must be at the same time as the study medication
-Patients with known kidney stones
-Patients with known heart block

# Study design

## Design

| | |
|---|---|
| Study phase: | 3 |
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Placebo |
| Primary purpose: | Treatment |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 05-12-2008 |
| Enrollment: | 92 |
| Type: | Actual |

## Medical products/devices used

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|---|---|
| Product type: | Medicine |
| Brand name: | avicel capsule |
| Generic name: | microkristallijne cellulose |
| Registration: | Yes - NL intended use |
| Product type: | Medicine |
| Brand name: | magnesiumoxide |
| Generic name: | magnesiumoxide |
| Registration: | Yes - NL outside intended use |

# Ethics review

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|---|---|
| Approved WMO Date: | 21-03-2008 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 08-07-2008 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |

# 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 |
|---|---|
| EudraCT | EUCTR2007-007072-42-NL |
| CCMO | NL20599.041.08 |