Magnesium oxide to reduce prostate motion.

Gepubliceerd: 18-12-2007 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24191

Bron
Nationaal Trial Register

Verkorte titel
Magnesium oxide to reduce prostate motion

Aandoening

1. Prostate cancer;

2. radiotherapy.

(NLD: prostaatkanker, bestraling).

Ondersteuning

Primaire sponsor: University Medical Center Utrecht, The Netherlands
Overige ondersteuning: University Medical Center Utrecht, The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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%.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Postbus 85500
University Medical Center Utrecht (UMC)
Department of Radiatherapy
I.M. Lips (M.D.)
Utrecht 3508
The Netherlands
+31 (0)88 755 8800

Wetenschappelijk

Postbus 85500
University Medical Center Utrecht (UMC)

Department of Radiatherapy
I.M. Lips (M.D.)
Utrecht 3508
The Netherlands
+31 (0)88 755 8800

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	Gerandomiseerd

Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-04-2008
Aantal proefpersonen:	184
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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

Resultaten

Samenvatting resultaten
N/A