Radiotherapy with or without ibandronate in the treatment of painful bone metastases of prostate cancer.

Gepubliceerd: 14-11-2005 Laatst bijgewerkt: 13-12-2022

The purpose of this study is to evaluate the efficacy of oral ibandronate (versus placebo) added to the standard radiotherapy regimen for painful bone metastases to reduce pain, to reduce the need of analgesics, and to reduce skeletal-related events...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20801

Bron
NTR

Verkorte titel
N/A

Aandoening

prostate cancer, metastases

Ondersteuning

Primaire sponsor: Roche Nederland
Overige ondersteuning: Roche Nederland

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary objective will be pain reduction on the pain scale (scale 0-10) at 12 weeks of treatment. Response of treatment will be defined as a reduction of at least two points of the pain scale.

Toelichting onderzoek

Achtergrond van het onderzoek

Although radiotherapy is highly effective to treat painful bone metastases of PC, the rate of re-treatment is considerable, and re-treatment of the same metastases needs to be done often after a short time and with a low response rate.
Ibandronate, 50 mg administered on a daily base for 6 months, might be effective to reduce pain from bone metastases, to reduce the need of analgesics, and to reduce the need of re-treatments with radiotherapy or other interventions.

Doel van het onderzoek

The purpose of this study is to evaluate the efficacy of oral ibandronate (versus placebo) added to the standard radiotherapy regimen for painful bone metastases to reduce pain, to reduce the need of analgesics, and to reduce skeletal-related events (impending fractures, need of repeated radiotherapy, or surgery).

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Ibandronaat tablet or placebo.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Karnofsky score „d60%;

2. Written informed consent;

3. Histologically proven PC with documented (bone scintigraphy, CT scan, MRI, or conventional X-Ray) bone metastases, without spinal cord/cauda equina compression;

4. Indication for analgesic radiotherapy;

5. Estimated life expectancy of „d6 months;

6. Clinically documented painful bone metastases;

7. Indication for analgesic radiotherapy for the painful bone metastases.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Previous treatment with any kind of bisphosphonates or radionuclides;

2. Hypercalcemia (serum calcium level >2.65 mmol/L), hypocalcemia (serum calcium level <2.2 mmol/L), impaired renal function (creatinine >266 umol/L; albumin >50 g/L), according to the medical charts;

3. Investigational drugs within 30 days before study entry;

4. Paget¡¦s disease;

5. Untreated esophagitis or gastric ulcer.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-12-2005
Aantal proefpersonen:	80
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	14-11-2005
Soort:	Eerste indiening

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	NL462
NTR-old	NTR503
Ander register	: N/A
ISRCTN	ISRCTN55471205

Resultaten

Samenvatting resultaten
N/A