Randomized controlled trial comparing conVEntional RadioTherapy with stereotactIC body radiotherapy in patients with spinAL metastases

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Our aim is to study whether the pain response after three months in patients with bone metastatic disease increases after SBRT in comparison to low dose EBRT.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Interventional

Summary

ID

NL-OMON44250

Source
ToetsingOnline

Brief title
VERTICAL study

Condition

- Bone disorders (excl congenital and fractures)
- Metastases

Synonym
bone metastases, metastatic bone disease

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: Bone metastases, Randomized Controlled Trial, Spinal metastases, Stereotactic Body Radiotherapy

Outcome measures

Primary outcome

The primary endpoint is pain control at three months after radiotherapy.

Secondary outcome

Secondary outcomes are the occurence of vertebral compression fracture (VCF)

and radiation induced myelopathy in spinal metastases, evaluation of local

tumour control and toxicity after SBRT, measurement of duration and rapidity of

pain relief, evaluation of quality of life, and evaluation of progression free

and overall survival.

Study description

Background summary

Bone metastases are a frequent distant manifestation of solid tumours, the most common areas include spine, pelvis, ribs and long bones of the upper and lower extremities. Patients with bone metastases mostly present with severe pain which reduces quality of life. The primary treatment for pain management is a single-fraction low dose external beam radiation therapy (EBRT), effective in achieving pain reduction in around 60% of patients, of whom 0-23% experience complete pain response. Recently, there is growing evidence that Stereotactic Body Radiotherapy (SBRT) achieves a much higher pain response due to the higher dose administered. In retrospective and a few prospective case series, SBRT for bone metastases has been demonstrated to be safe, and efficacious. However, no randomized controlled trials have been performed.

Study objective

Our aim is to study whether the pain response after three months in patients

with bone metastatic disease increases after SBRT in comparison to low dose EBRT.

Study design

We set up a randomized controlled trial, nested within the PRESENT cohort.

Intervention

Patients will undergo MRI-based, cone beam CT-guided SBRT and will receive a single dose of 18 Gray (Gy) on the visible metastasis, and 8 Gy on the bony compartment containing the metastasis (e.g. the affected vertebra or pedicle), or an equivalent fractionation schedule.

Study burden and risks

Patients who undergo SBRT may benefit from a more substantial pain response after SBRT. However, SBRT treatment time is longer than EBRT treatment time and in this study SBRT patients have to undergo 2 additional MRI scans which will last 15 minutes. There are no severe compications described for non-spine bone metastases. Furthermore, the two complications secondary to spine SBRT that must be discussed with the patient in order to ensure informed consent are VCF and radiation myelopathy. Since these patients are participants in the PRESENT cohort, and have already provided informed consent to fill out questionnaires on Patients Reported Outcomes, filling out questionnaires is not an additional burden to the patient.

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

Radiographic evidence of bone metastases;
Per spinal lesion no more than 3 consecutive spine segments involved with one unaffected vertebral body above and below;
No more than 2 painful lesions needing treatment;
Histologic proof of malignancy;
No compression of spinal cord;
No or mild neurological signs (i.e. radiculopathy, dermatomal sensory change, and muscle strength of involved extremity is Medical Research Counsil (MRC) 4/5);
Medically inoperable or patient refused surgery;
Karnofsky performance score (KPS) * 50;
Numeric rating scale (NRS) * 3;
Age * 18 years;
Written informed consent;
Filling out PRESENT-questionnaires.

Exclusion criteria

General exclusion criteria:
Radiosensitive histology such as multiple myeloma, lymphoma, small cell and germ cell;
MRI cannot be completed for any reason (in according with the MRI protocol of the Department of Radiology);
Impossible to delineate metastasis and organs at risk (OAR) due to artefacts on CT or MRI from previous surgical stabilisation;
Unable to undergo SBRT treatment, according to treating doctor*s opinion;
Severe, worsening or progressive neurological deficit;
Unstable bone requiring surgical stabilization;
Patient with < 3 months life expectancy;

Previous EBRT or SBRT to same location with bone metastases as target volume;
Chemotherapy or systemic radionuclide delivery within 24 hours before and after SBRT;
Patients with oligometastases who are selected for SBRT after multidisciplinary consultation;
Maximum diameter of target volume > 10 cm;
Extension of the tumour to the skin. ;Spinal metastases specific exclusion criteria:
Lesion in C1 and C2;
Epidural disease.;Specific exclusion criteria for bone metastases in the extremities:
Fixation material in target volume;
Impending fracture (if surgery or stabilisation is an option).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-01-2015
Enrollment:	110
Type:	Actual

Ethics review

Approved WMO Date:	12-11-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	11-03-2015

Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	17-07-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	23-09-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	10-02-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	23-05-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	28-12-2016
Application type:	Amendment
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
ClinicalTrials.gov	NCT02364115
CCMO	NL49316.041.14