

Stereotactic Body radiotherapy and pedicle screw fixation During one hospital visit for patients with symptomatic unstable spinal metastases: A randomized trial (BLEND RCT)

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To evaluate the (cost-)effectiveness of SBRT (with active dose-sparing of the surgical site) followed by surgical stabilization with or without decompression within 24 hours for the treatment of symptomatic, unstable metastases of the cervical,...

Ethical review	Approved WMO
Status	Recruitment started
Health condition type	Metastases
Study type	Interventional research previously applied in human subjects

Summary

ID

NL-OMON51812

Source

ToetsingOnline

Brief title

BLEND RCT

Condition

- Metastases
- Bone and joint therapeutic procedures

Synonym

Spinal metastases

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: ZonMW

Intervention

- Other intervention

Keyword: RCT, Same-day treatment, SBRT, Spinal metastases, Surgery

Explanation

N.a.

Outcome measures

Primary outcome

<p>Physical functioning, four weeks after the start of the treatment, which is a functional scale from the EORTC QLQ-C15-PAL questionnaire.</p>

Secondary outcome

<p>Secondary goals are to compare the pain response, duration of pain relief, length of hospital stay, time to return to systemic therapy, neurological deterioration, adverse events (e.g. wound complications), quality of life and survival between intervention and control. In addition, we will study the cost-effectiveness.</p>

Study description

Background summary

With improved survival rates, more patients will develop bone metastases, with the spine as the most common site for metastases. Spinal metastases can lead to devastating consequences including progressive, unremitting pain, and paralysis, and significantly impairs the patients' daily functioning and health related quality of life (HRQOL). Currently, patients with unstable spinal metastases receive surgical stabilization with or without decompression followed by CRT or SBRT after a time interval of 7 to 14 days (as soon as the wound is healed sufficiently) to prevent wound complications. However, this approach delays radiotherapy-induced pain relief and return to systemic therapy. In addition, surgical implants may cause imaging artefacts and may limit the dose behind the implants. Advancements in radiotherapy techniques makes stereotactic body radiation therapy (SBRT) possible. SBRT enables the delivery of high-dose radiation precisely to the spinal metastasis while keeping

the dose to the spinal cord and surrounding tissues, including the surgical area, low. As a result, the risk of wound complications is reduced and both treatments can be performed within a single hospital visit. This will result in earlier pain relief from irradiation and faster return to systemic therapy. The benefits are substantial, considering the relatively short life expectancy of these patients.

Study objective

To evaluate the (cost-)effectiveness of SBRT (with active dose-sparing of the surgical site) followed by surgical stabilization with or without decompression within 24 hours for the treatment of symptomatic, unstable metastases of the cervical, thoracic and/or lumbar spine on physical functioning after four weeks, compared with the standard of care (control arm; surgical stabilization with or without decompression followed by radiotherapy, i.e., CRT or SBRT).

Study design

This randomized controlled trial includes patients with bone metastases that meet the pre-specified in- and exclusion criteria for the current study. Patients who provided informed consent will be randomly allocated on a 1:1 basis for the intervention or control arm. Patients in the intervention arm will receive the new procedure, and patients in the control arm will receive standard of care.

Intervention

Same-day SBRT and surgical stabilization with or without decompression.

Study burden and risks

Both irradiation and surgical techniques are the current standard of care for patients with unstable spinal metastases and have been proven to be safe and effective in isolation. Both treatments are commonly practiced in our hospital. The preceding First-In-Man study demonstrated that delivery of single fraction SBRT followed by surgical stabilization with or without decompression within 24 hours is safe and feasible for the treatment of unstable spinal metastases. Also, no wound complications were observed.

Contacts

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Trial sites

Trial sites in the Netherlands

Universitair Medisch Centrum Utrecht

Target size: 50

St. Antonius Ziekenhuis

Target size: 10

Erasmus MC, Universitair Medisch Centrum Rotterdam

Target size: 20

OLVG

Target size: 12

Diakonessenhuis

Target size: 10

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Symptomatic (cervical, thoracic and/or lumbar) spinal metastases and impending spinal instability requiring radiotherapy and surgical stabilization
- Histologic proof of malignancy or radiographic/clinical characteristics indicating malignancy beyond reasonable doubt

- Radiographic evidence of spinal metastases
- Fit for (radio)surgery
- Age >18 years
- Written informed consent

Exclusion criteria

- SBRT cannot be delivered, e.g. in patients who cannot lie on the treatment table because of pain
- Surgery cannot be performed, e.g., multiple spinal metastases requiring surgical bridging of more than five vertebral levels
- Prior surgery or radiotherapy to the index levels
- Neurological deficits (ASIA C, B or A), or partial neurological deficits (ASIA D) with rapid progression (hours to days)
- Life expectancy of less than 3 months

Study design

Design

Study phase:	N/A
Study type:	Interventional research previously applied in human subjects
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Other type of control
Primary purpose:	Other

Recruitment

NL	
Recruitment status:	Recruitment started
Start date (anticipated):	30-11-2022
Enrollment:	92
Duration:	6 months (per patient)
Type:	Actual

Medical products/devices used

Product type: N.a.

IPD sharing statement

Plan to share IPD: Yes

Plan description

Op verzoek kunnen gegevens in een beveiligde omgeving gedeeld worden.

Ethics review

Approved WMO

Date: 19-09-2022

Application type: First submission

Review commission: METC NedMec

Approved WMO

Date: 18-06-2025

Application type: Amendment

Review commission: METC NedMec

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

ClinicalTrials.gov

CCMO

Research portal

ID

NCT05575323

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