# 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,...

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Metastases |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON51812

**Source**
ToetsingOnline

**Brief title**
BLEND RCT

### Condition

- Metastases

**Synonym**
Spinal metastases

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht
**Source(s) of monetary or material Support:** ZonMw

## Intervention

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

## Outcome measures

### Primary outcome

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

### Secondary outcome

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.

# 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 will be performed within the PRospective Evaluation of interventional StudiEs on boNe metastases (PRESENT) cohort including patients with bone metastases, according to the Trials within Cohorts (TwiCs) design. From patients who meet the pre-specified in- and exclusion criteria for the current study and who have provided informed consent for PRESENT, including randomization into future intervention studies, we randomly select patients on a 1:1 basis for the intervention arm. These patients will receive detailed information about the experimental treatment procedure, which they can accept or refuse to undergo. Informed consent is obtained from those patients accepting the intervention. Patients who were eligible but not selected for the intervention arm (i.e., control arm), will not be notified about the trial and their cohort data will be used comparatively. They are, however, aware of the fact that their clinical data and patient reported outcomes will be used for (comparative) research and they have given informed consent for that. These patients, as well as patients who refused to undergo the intervention, will receive the 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

## 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
• Participation in PRESENT cohort, including consent for randomization into

future trials
• 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 type: | Interventional |
| Intervention model: | Other |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 30-11-2022 |
| Enrollment: | 100 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 19-09-2022 |
| Application type: | First submission |
| 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 | ID |
|---|---|
| CCMO | NL80847.041.22 |