Feasibility of combined Focused Ultrasound and Radiotherapy treatment in patients with painful bone metastasis

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The PRE-FURTHER project aims to evaluate the feasibility of the combined EBRT and MR-HIFU treatment for relief of metastatic bone pain, and to optimize the combined treatment logistics.

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

Summary

ID

NL-OMON48418

Source
ToetsingOnline

Brief title
PRE-FURTHER

Condition

- Bone disorders (excl congenital and fractures)
- Metastases
- Bone and joint therapeutic procedures

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: European Commission Horizon 2020 programme

Intervention

Keyword: Bone metastases, MRI guided high intensity focused ultrasound, Radiotherapy

Outcome measures

Primary outcome

The main outcome of this study is feasibility of the procedure, in terms of

plannability as well as patient-tolerability of the combined treatment within a

short time frame (3 hours - 4 days interval).

Secondary outcome

In addition, pain relief and safety of the combined procedure will be

monitored.

Study description

Background summary

Magnetic Resonance Image guided High-Intensity Focused Ultrasound (MR-HIFU) is a non-invasive technique, which may induce rapid induction of pain relief in patients with painful bone metastases. In 2019, an international, H2020 funded randomized controlled trial (FURTHER) will be started comparing MR-HIFU with the current standard of care, external beam radiotherapy (EBRT), and the combination of both modalities in terms of rapid and long lasting pain relief. For this purpose, feasibility and optimal logistics of the combined treatment need to be evaluated.

Study objective

The PRE-FURTHER project aims to evaluate the feasibility of the combined EBRT and MR-HIFU treatment for relief of metastatic bone pain, and to optimize the combined treatment logistics.

Study design

Prospective case series (n = 6 - 10), stage I and IIA study according to the Innovation, Development, Evaluation, Assessment and Long term evaluation (IDEAL) recommendations.

Intervention

Following standard EBRT (single or multiple fraction), patients will receive one MR-HIFU treatment with the Profound Sonalleve MR-HIFU device on the most painful of their bone metastases. Patients will be followed up until 4 weeks after treatment. During follow-up they will be phoned around day 3, 7, 14, 21 and 28 to retrieve pain scores, pain medication and (serious) adverse events. At day 3 the patient*s experience with the combined treatment will also be inquired.

Study burden and risks

In terms of benefits, patients participating in this study may experience a more rapid and longer lasting pain relief as a result of the MR-HIFU intervention. In terms of burden, patients in most cases will need to pay an extra visit to the hospital, undergo a rather lengthy additional intervention (MR-HIFU treatment), under conscious sedation. In addition, they are contacted regularly by phone. Serious adverse events due to the combined treatment are not to be expected.

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

- Men and women with age * 18 years;
- Patient capable of giving informed consent and able to attend study visits;
- Uncomplicated painful bone metastases;
- Weight < 140kg and able to fit in the MRI gantry;
- Radiologic evidence of bone metastases from any solid tumor;
- Pain is localized to the targeted area, or is likely to be referred pain arising from the targeted area;
- Pain related to the target lesion is refractory to less invasive treatments for pain relief;
- Multiple metastatic lesions, with one predominantly painful lesion (><=2 points higher pain score than other lesions). The lesion should be clearly distinguishable form other painful lesions;
- Device accessible tumors: extremities (excluding joints), pelvis, shoulders, posterior vertebral spine below L5, in selected cases ribs and sternum;
- Target lesion maximum dimension * 8cm;
- Intended target volume visible by non-contrast MR imaging;
- Distance between target and skin * 1cm;
- Numeric Rating Scale (NRS) score >< = 4 or equivalent;
- Life expectancy >3 months.

Exclusion criteria

- Planned treatment lesion is a primary bone tumor or due to lymphoma, multiple myeloma, or leukemia;
- Communication barrier present;
- Patient enrolled in another clinical study related to bone metastases treatment or pain relief treatment;
- Unable to tolerate required stationary position during treatment despite adequate pain medication;
- Need for surgery;
- Pregnant woman;
- Pain related to target lesion is predominantly due to fracture or impending fracture;

- Pain related to target lesion is due to involvement of a neighboring major nerve by the metastatic tumor (cord or nerve compression);
- Target < 3cm from bladder / bowel / nerve along the beam path and < 1cm in the plane orthogonal to the beam;
- Target in contact with hollow viscera;
- Target located in skull, joints, ribs (when HIFU beam overlapping with lung), spine (excluding sacrum which is allowed) or sternum;
- Internal or external fixation device along the proposed HIFU beam path or at the target;
- MRI contraindicated (e.g. paramagnetic implants, pacemaker, claustrophobia);
- MRI contrast agent contraindicated (e.g. previous anaphylaxis or Glomerular Filtration Rate < 20 ml/min/1.73m2);
- Sedation contraindicated;
- Previous surgery or minimally invasive treatment at targeted site within the last three months;
- Clinically relevant medical history or abnormal physical findings that could interfere with the safety of the participant as judged by the treating physician or investigator;
- Karnofsky performance score (KPS) < 60%;
- Oligometastatic disease planned for curative treatment;
- Indication for stereotactic radiotherapy (e.g. patients with radioresistent histology such as renal cell, melanoma, sarcoma metastases);
- History of photodermatoses (of the skin overlying the target area);
- Need for remineralisation;
- Previous radiation to same site.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-04-2019
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Sonalleve MR-HIFU system Bone Application
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	27-02-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	03-07-2019
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
CCMO	NL68441.041.19