Magnetic Resonance-Guided High Intensity Focused Ultrasound for Palliation of Painful Skeletal Metastases - a Multicenter Study.

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The primary objective of this study is to evaluate effectiveness of the Philips Sonalleve MR-HIFU device for the palliation of pain in patients with bone metastases.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint injuries
Study type	Observational invasive

Summary

ID

NL-OMON39361

Source
ToetsingOnline

Brief title
MR-HIFU for Bone Metastases - Multicenter.

Condition

- Bone and joint injuries
- Metastases

Synonym
bone disseminations., Bone metastases

Research involving
Human

Sponsors and support

Primary sponsor: Philips Medical Systems, MR Finland

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: MR guided focused ultrasound., Non invasive therapy., Painful skeletal metastases.

Outcome measures

Primary outcome

The primary outcome measure is the pain response (dichotomous outcome) 30 days after treatment. Pain response is determined by comparing pain score (NRS) and pain medication at 30 days after treatment with baseline values in the same patient.

Secondary outcome

Incidence of adverse events.

Quality-of-life.

Time-related aspects of pain response.

Changes in size/enhancement pattern on x-ray and MRI.

Study description

Background summary

Metastatic bone pain occurs frequently in cancer patients. In addition to pain medication, radiotherapy is the standard of care for palliative treatment of metastatic bone pain. In around 30-40% of patients no pain response occurs after radiotherapy. Recurrence is also common (around 50%) after initial response to radiotherapy. Reirradiation is not always possible due to dose accumulation, and when applied response occurs in around 60%.
Magnetic Resonance Imaging-guided High Intensity Focused Ultrasound (MR-HIFU) is a new palliative treatment for metastatic bone pain. In this treatment ultrasound is used to locally heat tissue under MRI-guidance. The main mechanism is thought to be local bone denervation, caused by the heat denaturation of the periosteum. The importance of this therapy is that it

offers a non-invasive, focal therapy, avoiding side-effects to surrounding normal tissue or the need for needle insertion as with RF ablation.
The null hypothesis is that 40% of patients will exhibit pain response (partial or complete response) at 30 days after treatment (assuming MR-HIFU is not effective). The alternative hypothesis is that > 60% of patients will exhibit pain response at 30 days after treatment.

Study objective

The primary objective of this study is to evaluate effectiveness of the Philips Sonalleve MR-HIFU device for the palliation of pain in patients with bone metastases.

Study design

This study is a multi-center, single arm, non-randomized, non-blinded trial.

Intervention

All patients will receive one session of MR-HIFU treatment with the Philips Sonalleve MR-HIFU device on the most painful bone metastasis.

Study burden and risks

Patients will be required to attend up to seven site visits. The total duration of the study for a single patient will be around four months, including the time required for informed consent and screening and a follow-up period of up to 90 days.
The first 30 days after treatment patients are asked to keep a diary in which the pain scores and pain medication is required. In addition, they will be asked to complete questionnaires (about pain and quality of life) on up to six occasions. Up to five clinical examinations will be performed and one blood sample will be taken. Patients will undergo five MRI scans, four x-ray images and one CT scan. The radiation exposure is considered acceptable since this is relatively low and the patients that will be treated do not have a long life expectancy in general. During MR-HIFU treatment there is a risk of increased temporary pain. The pain medication and/or sedation will be adjusted accordingly.
Patients will probably experience partial or total relief from the pain arising from the targeted metastasis. Furthermore, patients enrolling in this study will help determine the efficacy and safety of a new non-invasion therapy for pain palliation in bone metastases.
It is deemed that the potential benefits of this study, both to the individual patient, as manifested by potential pain relief at the targeted lesion, and to the wider patient community, as manifested by potential wider availability of a non-invasive option for pain palliation in bone metastases, outweighs the

potential risks.

Contacts

Public
Philips Medical Systems, MR Finland

Äyritie 4
Vantaa FI-01510
FI
Scientific
Philips Medical Systems, MR Finland

Äyritie 4
Vantaa FI-01510
FI

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.
Capable of giving informed consent and able to attend study visits.
Weight < 140 kg.
Radiologic evidence of bone metastases from any solid tumor.
Diagnosis of dominant painful bone metastasis (NRS * 4), either refractory to standard of care (including radiotherapy and optimal pain medication) or standard of care is refused by patient or contra-indicated.
Patient has been on stable pain medication for at least 1 week prior to HIFU treatment date.
Pain is localized to the targeted area, or is likely to be referred pain arising from the targeted

area.
Patient has 1-3 painful lesions, and only the most painful lesion will be treated.
Intended Target Volume accessible for MR-HIFU procedure.
Target lesion maximum dimension * 8 cm.
Intended target volume visible by non-contrast MR imaging.
Distance between target and skin * 1 cm.
Patient is able to communicate sensation during MR-HIFU treatment.
MR-HIFU treatment date * 4 weeks from last local treatment of the target lesion.

Exclusion criteria

Planned treatment lesion is a primary bone tumor or due to lymphoma 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.
Need for surgical stabilization in case of (impending) fracture (lytic lesion in weight-bearing bone larger than 50% of bone diameter).
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 < 3 cm from bladder / bowel / nerve along the beam path and < 1 cm 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.
Scar along proposed HIFU beam path.
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 GFR < 30 ml/min/1.73m2).
Sedation contraindicated.
Previous surgery or minimally invasive treatment at targeted site.
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.

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-10-2012
Enrollment:	14
Type:	Actual

Medical products/devices used

Generic name:	MR High Intensity Focused Ultrasound.
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	18-07-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	21-11-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	21-07-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	13-08-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	12-11-2014
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	NCT01586273
CCMO	NL39330.041.12