Focused Ultrasound and Radiotherapy for Noninvasive Palliative Pain Treatment in Patients with Bone Metastases

Published: 22-01-2020
Last updated: 24-05-2024

The FURTHER study aims to evaluate the effectiveness and cost-effectiveness of MR-HIFU (alone or in combination with EBRT) compared to EBRT alone, the standard-of-care, as a palliative treatment option to relieve CIBP.

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

Summary

ID

NL-OMON52529

Source
ToetsingOnline

Brief title
FURTHER

Condition

- Metastases

Synonym
Bonemetastases, metastasis in the bone

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Eurpeon Commission Horizon 2020 programme

Intervention

Keyword: Bone metastases, MR-HIFU, Pain palliation, Radiotherapy

Outcome measures

Primary outcome

Primary outcomes of the trial will be pain response at 14 days after completion of the treatment, and pain response at 14 days after inclusion. Secondary outcomes include pain scores, toxicity, adverse events, quality of life and survival in the first 6 months after treatment, and cost-effectiveness of the treatments.

Secondary outcome

Secondary outcomes include pain scores, toxicity, adverse events, quality of life and survival in the first 6 months after treatment, and cost-effectiveness of the treatments.

Study description

Background summary

Cancer induced bone pain (CIBP) as a result of bone metastases strongly interferes with quality of life and daily functioning of patients with advanced cancer. The current standard of care for patients with painful bone metastasis includes palliative external beam radiotherapy (EBRT). While EBRT is a well-established treatment option, it takes up to 4-6 weeks for EBRT to induce optimal pain relief, and 30-40% of patients do not respond to EBRT. Pain palliation may be improved by including magnetic resonance image guided high intensity focused ultrasound (MR-HIFU) as alternative or in addition to EBRT.

Study objective

The FURTHER study aims to evaluate the effectiveness and cost-effectiveness of MR-HIFU (alone or in combination with EBRT) compared to EBRT alone, the

standard-of-care, as a palliative treatment option to relieve CIBP.

Study design

The FURTHER study consists of a prospective, multicenter, three-armed randomized controlled trial (FURTHER RCT) and a patient registry arm (FURTHER Registry), performed in six hospitals in four European countries, all of which are partners in the FURTHER consortium. The UMC Utrecht is coordinating center. A total of 216 patients with painful bone metastases will be randomized in a 1:1:1 ratio to receive EBRT only, MR-HIFU only, or EBRT followed by MR-HIFU. In the Netherlands, we expect to enroll a minimum of 70 patients, and a maximum of 120 patients in three Dutch study sites. Within the FURTHER Registry, data of around 60-90 patients will be captured.

Intervention

The intervention under study is MR-HIFU alone or in combination with EBRT. The intervention is aimed at rapid and persistent relief of CIBP.

Study burden and risks

In terms of benefits, patients participating in this study may experience a more rapid pain relief as a result of the MR-HIFU intervention. In terms of burden, patients in the intervention arms will possibly need to pay an extra visit or visits to the hospital, they will undergo a rather lengthy (additional) intervention (MR-HIFU treatment) under sedation or anaesthesia. In addition, all study participants will have to fill in a daily pain diary during the first 21 days after treatment and quality of life questionnaires at six time-points in the follow up period. Serious adverse events due to the intervention are not to be expected.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age >= 18 years
Patient capable of giving informed consent
Painful metastatic bone lesion (NRS >= 2)
Patient-localised pain with a distinct pathological substrate on recent CT/MRI
Target lesion location is >75% accessible for MR-HIFU
Participant able to fit in the MRI gantry
Reasonable performance score (KPS > 50% or Zubrod/ECOG/WHO < 3)
Life expectancy > 3 months

Exclusion criteria

Need for surgery of targeted location due to (impending) pathological fracture
Unavoidable critical structures or dense tissues in target area *
Contra indications MRI or sedation/anaesthesia
Participant enrolled in another clinical interventional study related to bone metastases treatment or pain relief treatment
Clinically relevant medical history or physical findings that could interfere with the patient's safety as judged by the treating physician

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:	Recruiting
Start date (anticipated):	02-11-2020
Enrollment:	65
Type:	Actual

Ethics review

Approved WMO Date:	22-01-2020
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	22-09-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	05-12-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	08-05-2024
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	ID
CCMO	NL71303.041.19