CT/MR guided cryoablation for painful bone metastasis: an observational trial.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Synovial and bursal disorders
Study type	Interventional

Summary

ID

NL-OMON34458

Source
ToetsingOnline

Brief title
nvt

Condition

- Synovial and bursal disorders
- Metastases
- Bone and joint therapeutic procedures

Synonym
malignancy, metastases

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: bone, cryoablation, image-guided, metastases

Outcome measures

Primary outcome

The feasibility of CT/MR guided cryoablation in vivo in patients with painful bone metastasis is described by changes in pain intensity. These results will be correlated with a matched group of the Dutch bone metastasis study; the endpoint is response to pain.

Secondary outcome

The accuracy of cryoprobe(s) placement under CT/MR image guidance is given by measuring the 3D error at the images retrospectively. The correlation between the MR results from multimodality MR and the CT/MR imaging will be compared with the clinical results.

Study description

Background summary

Pain is a common symptom in cancer patients; up to 86% of the patients with advanced cancer suffer from pain. Pain is caused by bone metastasis in 31% to 42% of these patients. Radiotherapy is the current palliative treatment modality of choice in our hospital. This project has the goal to test the feasibility of a novel focal treatment for these patients, namely CT/MR guided cryoablation. Percutaneous cryoablation is a minimally invasive technique in which freezing is used to destroy tissue. The freezing is seen on imaging as an iceball. Cell death being reliable occurring 3mm deep near the edge. The project combines three novel approaches implemented at our institution for painful bone metastasis: MR techniques to identify the bone metastasis, CT/MR guided cryoprobe(s) placement, and ablation under MR control.
A patient group of twenty patients will be included in this observational study. We will include patients with no more than two painful bone metastasis. The lesion must be osteolytic, not larger than 3 cm and it must be possible to

reach the lesion with 5 mm distance from the spinal cord, nerves, and artery of Adamkiewicz.
The suggested technique holds the promise to provide an alternative treatment for bone metastasis in our hospital, with less side effects to be expected compared with radiation therapy (id est risk of a pathological fracture and spinal cord compression). Potential complications will be recorded and the response will be calculated considering changes in pain intensity.
The main objective of the study was to prove the effectiveness of cryoablation in palliating pain and correlate the patients with a matched group of the Dutch bone metastasis study. The secondary objectives are to determine the accuracy of cryoprobe(s) placement under CT/MR guidance by measuring the 3D error at the multimodality MR and CT/MR images retrospectively. And to correlate the MR results from multimodality MR and the iceball on CT/MR imaging during the ablation process with the pain control.

Study objective

The main objective of the study was to prove the effectiveness of cryoablation in palliating pain and correlate the patients with a matched group of the Dutch bone metastasis study. The secondary objectives are to determine the accuracy of cryoprobe(s) placement under CT/MR guidance by measuring the 3D error at the multimodality MR and CT/MR images retrospectively. And to correlate the MR results from multimodality MR and the iceball on CT/MR imaging during the ablation process with the pain control.

Study design

A prospective, observational non randomized study. This trial will be run at the UMC St Radboud, 20 patients will be included at the UMC st Radboud from October 2010 to October 2011.

Intervention

The patient group will undergo additional CT/MR guided cryoablation.

Study burden and risks

Potential patient risks in this study as mentioned by complications of MR imaging (burden of heating and noise, risks of contrast reactions against gadolinium), CT imaging (expected addition radiation cancer risk <0.02 Sv (see K5), focal cryoablation (hemorrhage, inflammation) or serious unexpected events and patient burden in form of time investment are outweighed by potential benefits for patients.

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

• 18 years of age or more
• Histologically proven malignancy
• Signed informed consent by patient
• Pain intensity of at least 2. [18]
• Lesion must be osteolytic
• Lesion should be reachable, with a distance of 5 mm of the spinal cord, nerves, braines and artery of Adamkiewicz.
• Bone metastasis smaller than 3 cm.

Exclusion criteria

• Patients unable to undergo MR imaging, including those with contra-indications
• Any metallic implant or device that distorts local magnetic field and compromises the quality of MR imaging
• Metastases of malignant melanoma or renal cell carcinoma because these are considered to express a different biological behaviour.
• Metastases in the cervical spine because it is believed that large fractions might lead to a radiation induced myelopathy and thus cannot be compared with the matched group.
• Adult with more than two painful bone metastasis
• Previous treatment for painful bone metastasis
• Metastases that need stabilization with cementoplasty.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2010
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	30-11-2011

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL33800.091.10