Post-operative RadioTherapy for patients with metastases of the long bones

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The OPTIMAL-PORT study aims to demonstrate the non-inferiority of *surgery only* compared to surgery with adjuvant radiotherapy as treatment for impending and actual pathological fractures on the pain experienced by patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Musculoskeletal and connective tissue neoplasms
Study type	Interventional

Summary

ID

NL-OMON45060

Source
ToetsingOnline

Brief title
OPTIMAL-PORT Study

Condition

- Musculoskeletal and connective tissue neoplasms

Synonym
metastatic bone disease, skeletal metastasis

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Alpe d'HuZes

Intervention

Keyword: bone metastases, quality of life, radiotherapy, surgery

Outcome measures

Primary outcome

Primary endpoint is patient reported pain according to a numeric rating scale

(NRS).

Secondary outcome

Clinical functioning, radiological status, complications (including revisions)

and survival are secondary endpoints.

Study description

Background summary

Bone metastases arise in 50% of all patients diagnosed with carcinoma, increasing up to 70% in patients with breast and prostate cancer. The lesions can cause pain and fractures, leading to diminished quality of life and poorer survival. Current knowledge concerning adequate, personalized treatment of metastatic lesions of the long bones in patients with disseminated cancer is insufficient and inconclusive due to lack of large, prospective series with patient reported outcome measures. One of the debatable issues is the effectiveness of postoperative radiotherapy. It has become common practise due to professional opinion, but research evidence is lacking. It is thought that adjuvant radiotherapy improves the durability of an implant, prevents progression of the lesion, promotes bone healing, improves limb function, minimises pain and reduces the need for reoperations, however none of these are certain. Moreover, it is a burden on patient's quality of life (e.g. multiple extra hospital visits) causing toxicity and possible side effects (e.g. skin irritation). The true beneficial effect, weighing up the possible pros and certain cons, of adjuvant radiotherapy is thus unknown.

Study objective

The OPTIMAL-PORT study aims to demonstrate the non-inferiority of *surgery only* compared to surgery with adjuvant radiotherapy as treatment for impending

and actual pathological fractures on the pain experienced by patients.

Study design

A multicentre, prospective, randomised non-inferiority trial nested within the OPTIMAL study.

Intervention

One study group (A) will receive surgery only; the other study group (B) will receive surgery with adjuvant radiotherapy.

Study burden and risks

Patients participating in the PORT study will perhaps not directly benefit from their participation. Due to the fact that there is still much uncertainty concerning the necessity of post-operative radiotherapy for quality of life, it is possible that there is benefit in either group. Participation will in any case contribute to deriving patient-specific treatment modalities for future patients with bone metastases of the long bones. Risks associated with participation are related to the local consequences of (lack of) radiotherapy and to the quality of life.

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

- Aged 18 or older
- Receive surgical treatment (prosthesis, intramedullary nail, plate, curettage with/without cement) with palliative intent for a pathologic fracture or impending pathologic fracture of the extremities (humerus/femur and further distal) due to metastatic bone disease
- Radiographic or histologic proof of metastatic bone disease
- Histologic diagnosis of the primary tumour or * if the diagnosis is unknown - at least adequate diagnostic investigations into the origin of the metastasis (e.g. dissemination imaging, histology, biopsy)

Exclusion criteria

- Communication with patient is hampered (e.g. language barrier, severe cognitive impairment, dementia)
- The treated lesion originates from multiple myeloma, solitary plasmacytoma or lymphoma of bone
- Further radiotherapy is considered inappropriate (> 2 series RT on current lesion)
- Physically unable to undergo post-operative RT treatment, according to treating doctor*s opinion
- Absolute need for post-operative treatment with radiotherapy, specify reason:
o Pain
o Extent of bone lesion (outside surgical field)
o Soft tissue involvement
o Curative intent of treatment

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:	Recruitment stopped
Start date (anticipated):	01-10-2015
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO

Date:	24-11-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	28-04-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date:	20-07-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	28-02-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL54480.058.15

Study results

Date completed:	23-01-2019
Results posted:	12-04-2019
Actual enrolment:	6

First publication
01-01-1900