# The OPTIMAL Study: a prospective cohort of patients with bone metastases of the long bones

Published: 24-11-2015
Last updated: 19-04-2024

The OPTIMAL cohort aims to describe the quality of life and pain perception of patients after local treatment (radiotherapy and/or surgery) of metastases of the long bones, for both the entire cohort as well as for specific treatments separately....

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Musculoskeletal and connective tissue neoplasms |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON47589

**Source**
ToetsingOnline

**Brief title**
OPTIMAL 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 endpoints are patient reported quality of life (including functioning)

and pain levels.

### Secondary outcome

Complications, 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.

### Study objective

The OPTIMAL cohort aims to describe the quality of life and pain perception of patients after local treatment (radiotherapy and/or surgery) of metastases of the long bones, for both the entire cohort as well as for specific treatments separately. With this a more personalized treatment for metastases in the long bones based on expected survival and impending fracture risk can be provided in order to improve functioning and the quality of life for the remaining lifetime in patients with disseminated cancer.

### Study design

Observational, prospective, multicentre cohort study.

### Study burden and risks

Patients in the OPTIMAL cohort will perhaps not directly benefit from their participation. Participation will contribute to deriving patient-specific treatment modalities for future patients with bone metastases of the long bones. Risks associated with participation in the prospective cohort are considered negligible due to the observational nature of the study. The burden for the patients lies in completion of questionnaires, which is considered to be in proportion with the potential value of this research.

## Contacts

**Public**
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333ZA
NL
**Scientific**
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333ZA
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

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

### Inclusion criteria

- Aged 18 or older
- 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)
- Bone metastasis deriving from the bones of the extremities

### Exclusion criteria

- Primary bone tumours (benign and/or malignant)
- No informed consent signed
- Communication with patient is hampered (e.g. language barrier, severe cognitive impairment, dementia)

## Study design

### Design

**Study type:** Observational non invasive

| | |
|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Prevention |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 20-01-2016 |
| Enrollment: | 1800 |
| Type: | Actual |

## Ethics review

Approved WMO

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

Approved WMO

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

Approved WMO

| | |
|---|---|
| Date: | 20-12-2016 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
| | metc-ldd@lumc.nl |

Approved WMO

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

Approved WMO

| | |
|---|---|
| Date: | 25-10-2017 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
| | metc-ldd@lumc.nl |

Approved WMO

| | |
|---|---|
| Date: | 14-01-2019 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
| | metc-ldd@lumc.nl |

Approved WMO

| | |
|---|---|
| Date: | 14-05-2019 |
| 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 | NL54439.058.15 |