

PRospective Evaluation of interventional StudiEs on boNe meTastases

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Observational non invasive

Summary

ID

NL-OMON53152

Source

ToetsingOnline

Brief title

PRESENT+

Condition

- Bone disorders (excl congenital and fractures)
- Metastases

Synonym

Bone metastases, metastatic bone disease

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

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

Intervention

Keyword: Bone metastases, Multi-trial facility, Prediction

Outcome measures

Primary outcome

Clinical parameters (co-morbidity, oncological history, symptoms, imaging, technical and treatment data), clinical endpoints (pain response, toxicity and survival) and patient reported outcomes (pain scores and QoL and satisfaction with care).

Secondary outcome

Not applicable.

Study description

Background summary

Bone metastases are frequent distant manifestations of cancer, with pain as a common and devastating consequence. The primary treatment for painful bone metastases, external beam radiation therapy, is moderately effective: about 60% of patients who undergo conventional radiotherapy experience (partial) pain relief. Several factors associated with treatment failure have been identified, but no attempts have been made to collapse these factors into a clinically useful prediction tool to predict treatment response. In addition, to aid in therapy selection based on expected survival time, development of survival models is essential. Finally, we need innovative treatments as alternatives or additive to standard treatment options to improve quality of life (QoL). For these reasons, we set up the PRESENT cohort study.

Study objective

The PRESENT cohort has three goals: first, the cohort provides detailed, clinical information for example therapy response and quality of life and satisfaction with care, second, the PRESENT cohort provides a framework for multiple, concurrent, randomized interventions comparisons, and finally, the cohort serves to develop prediction models.

Study design

Observational, prospective cohort study, according to the *cohort multiple Randomised Controlled Trial* (cmRCT) design.

Study burden and risks

Patients will not experience direct benefit from participation in the PRESENT cohort. By participating, patients will contribute to the evidence on clinical and environmental factors associated with treatment outcome, QoL, satisfaction with care and survival. This will lead to better and a more personalized cancer care for future patients. Risks associated by participating in the PRESENT cohort study are negligible since it is observational.

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

Histologic proof of malignancy;
Radiographic or histologic proof of metastatic bone disease;
Referred to the Department of Radiotherapy or Orthopedic Surgery;
18 years and older;
Informed consent - at least - for use of routinely collected clinical data.

Exclusion criteria

Mentally incompetent patients;
Life expectancy of less than a week indicated by the treating physician.

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 07-01-2015

Enrollment: 11000

Type: Actual

Ethics review

Approved WMO

Date: 11-11-2014

Application type: First submission

Review commission: METC NedMec

Approved WMO	
Date:	25-02-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	29-09-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	18-01-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	31-08-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	03-04-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	19-04-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	14-05-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	
Date:	15-01-2025
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

ClinicalTrials.gov
CCMO

ID

NCT02356497
NL49273.041.14