

VERtebroplasty versus Radiotherapy As palliative treatment of vertebral metastases of Multiple Myeloma (M. Kahler)

Submission date 27/06/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/06/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 26/09/2007	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Acronym

VERAMM

Study objectives

Vertebroplasty improves the quality of life of the individual patient by increased pain reduction and restoration of mobility. Vertebroplasty also reduces costs, as it decreases the number of inpatient days, the number of outpatient visits and follow-up treatments, and the need for home care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The VERAMM trial was approved by the Medical Ethics Committee Erasmus MC (METC) on the 15th March 2007 (ref: MEC-2007-033).

Study design

Randomised, active controlled, parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Spinal metastases, vertebroplasty, multiple myeloma

Interventions

Arm I (control): radiotherapy (20 Gy) of affected vertebrae

Arm II: vertebroplasty of affected vertebrae

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Degree of pain (VAS-pain score, scale: 0 - 10), measured at day 0 (pre-treatment), day 0 (post-treatment), day 7, week 4, week 12, month 6 and year 1
2. Use of pain medication, measured at day 0 (pre-treatment), day 0 (post-treatment), day 7, week 4, week 12, month 6 and year 1

Secondary outcome measures

1. Initial technical success and complications, measured at day 0 (post-treatment) and week 4 respectively
2. Mobility (Oswestry-daily activity scale), measured at day 0 (pre-treatment), day 7, week 4, week 12, month 6 and year 1
3. Quality of life (questionnaires: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire on Myeloma [EORTC QLQ-MY24], 36-item Short Form health survey [SF-36]), measured at day 0 (pre-treatment), day 7, week 4, week 12, month 6 and year 1
4. Collapse of treated vertebrae (lateral X-WK), measured at day 0 (pre-treatment), week 4, week 12, month 6 and year 1
5. Mortality, measured at year 1
6. Direct medical costs (e.g. procedure costs, hospitalisation days, pain medication, secondary interventions, revalidation or nursing home costs, follow-up), measured at year 1

Overall study start date

04/06/2007

Completion date

01/03/2010

Eligibility**Key inclusion criteria**

1. Persistent pain caused by vertebral metastases from myeloma (including plasmacytoma) with Visual Analogue Scale (VAS) score greater than 4 (scale: 1-10)
2. Informed consent
3. Older than 18 years

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

Key exclusion criteria

1. Greater than four affected vertebrae
2. Vertebral fracture through back wall with retropulsion that consumes more than 33% of the spinal channel
3. Myelum compression with neurological degeneration: Frankel A/B
4. Epiduritis
5. Incurable coagulopathy
6. Karnofsky score less than 30 (moribund)

Date of first enrolment

04/06/2007

Date of final enrolment

01/03/2010

Locations**Countries of recruitment**

Netherlands

Study participating centre

Department of Radiology Hs-220

Rotterdam

Netherlands

3015 CE

Sponsor information**Organisation**

Erasmus Medical Centre (The Netherlands)

Sponsor details

Department of Radiology

s-Gravendijkwal 230

Rotterdam

Netherlands

3015 CE

Sponsor type

Hospital/treatment centre

Website

<http://www.erasmusmc.nl/content/englishindex.htm>

ROR

<https://ror.org/018906e22>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Erasmus Medical Centre (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration