

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

Submission date 27/06/2007	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 27/06/2007	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 26/09/2007	Condition category Cancer	☐ Individual participant data ☐ 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

Protocol serial number

CCMO NL14746.078.07; Erasmus MC METC 2007-033

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Not Specified

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)

ROR

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Erasmus Medical Centre (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration