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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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. Incorrigible 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