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Myeloma VII - myelomatosis therapy trial

Submission date 25/10/2000	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/10/2000	**Overall study status** Completed	
Last Edited 19/08/2009	**Condition category** Cancer	

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
G8223452

Study information

Scientific Title

Study objectives
To compare ABCM for plateau induction with alpha IFN maintenance vs. a three-phase regimen of C-VAMP, high dose melphalan (with autologous bone marrow/peripheral blood stem cell support as appropriate) and alpha IFN maintenance. To compare toxicity profiles in the two arms, to address the issue of quality of life, to address the issue of health economics, to investigate cellular changes by means of linked studies of morphology, phenotyping and cytogenetics before and after treatment and at relapse.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Leukaemia

Interventions
ABCM for plateau induction with alpha Interferon (IFN) maintenance/a three-phase regimen of C-VAMP, high dose melphalan (with autologous bone marrow/peripheral blood stem cell support as appropriate) and alpha IFN maintenance

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Overall survival

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/1993

Completion date
20/10/2000

Eligibility

Key inclusion criteria
1. They have definite myelomatosis requiring chemotherapy and fulfilling at least two of the three following criteria: bone marrow aspirate and/or trephine showing the presence of a neoplastic plasma cell infiltrate and/or microplasmacytomas, a paraprotein present in blood and /or urine
2. They have definite lytic bone lesions
3. They are aged under 65 years
4. They are able to tolerate a daily fluid intake of not less than 3 litres
5. The physician is satisfied it would be appropriate to receive any of specified treatments

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
750

Key exclusion criteria
1. Patients have equivocal myelomatosis (these should be registered but will not receive treatment - if disease progresses then they may be entered into the main trial)
2. They have previous malignancies except non-melanoma skin tumours or in situ carcinomas
3. Had previous treatment except minimal local radiotherapy to relieve bone pain
4. If have a life threatening disease unrelated to myelomastosis.

Date of first enrolment
01/09/1993

Date of final enrolment
20/10/2000

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Haematology
Leeds
United Kingdom
LS1 3EX

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
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Sponsor type
Research council

Website
http://www.mrc.ac.uk

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/05/2003		Yes	No