VIIIth myelomatosis trial

Submission date Prospectively registered Recruitment status 25/10/2000 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 25/10/2000 Completed [X] Results [] Individual participant data **Condition category Last Edited** 11/01/2011 Cancer

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number G8223452

Study information

Scientific Title

Study objectives

Not provided at time of registration

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

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Myelomatosis

Interventions

All patients receive three courses of chemotherapy with adriamycin, carmustine, melphan and cyclophosphamide (ABCM), cycle to be repeated every 6 weeks. Patients who in whom there are no signs of disease progression and who fulfil all the entry criteria are randomised to one of two treatment regimens:

- 1. ABCM REGIMEN: Chemotherapy with ABCM, cycle to be repeated every 6 weeks. Treatment is stopped when the patient reaches plateau phase provided they have received at least four courses of ABCM.
- 2. ORAL C WEEKLY REGIMEN: Oral cyclophosphamide given as a single dose every 7 days plus prednisolone given on alternative days for 6 weeks. Weekly oral cyclophosphamide is continued until the patient reaches plateau phase and has received either three courses of ABCM and a minimum of 8 weeks of oral cyclophosphamide (if less than three courses of ABCM were given, 6 months chemotherapy), there is disease progression or the patient can no longer tolerate treatment.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Adriamycin, carmustine, melphan and cyclophosphamide (ABCM)

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s))

Not provided at time of registration

Completion date

31/12/2002

Eligibility

Key inclusion criteria

- 1. Patients with definite myelomatosis requiring chemotherapy in the judgement of the physician 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 the blood and/or urine; Definite lytic bone lesions
- 2. Aged less than 65 years
- 3. Patients with equivocal myelomatosis are excluded
- 4. No previous cytotoxic chemotherapy, except prednisolone or other corticosteroids to relieve fluid-unresponsive hypercalcaemia or minimal local radiotherapy to relieve bone pain
- 5. No medical contraindications to protocol treatments
- 6. Patients must have a neutrophil count of at least 1.3 x 10E9/l and a platelet count of at least $75 \times 10E9/l$
- 7. Patients must be able to tolerate a daily fluid intake of not less than 3 litres, evidence of renal insufficiency following pre-treatment re-hydration does not necessarily exclude
- 8. Patients must be apyrexial and free from infection

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/11/1993

Date of final enrolment

31/12/2002

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University of Birmingham

Birmingham United Kingdom B15 2TT

Sponsor information

Organisation

Medical Research Council (MRC) (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

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	20/12/2005		Yes	No

Results article results 15/09/2006 Yes No