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VIIIth myelomatosis 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 11/01/2011	**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

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 x 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, Medical Research Committee and Advisory 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				

Results article	results	20/12/2005	Yes	No
Results article		15/09/2006	Yes	No