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Medical Research Council sixth myelomatosis trial for previously untreated patients: ABCM with or without clodronate

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 10/10/2012	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr - -

Contact details
UKCCCR Register Co-ordinator
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MRC MYEL VIA

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Plasma cell neoplasms

Interventions
Patients are randomised to one of two treatment regimens:
1. Regimen A: Induction chemotherapy with adriamycin, carmustine, melphan and cyclophosphamide (ABCM) repeated every 6 weeks plus daily oral placebo.
2. Regimen B: Induction chemotherapy with ABCM repeated every 6 weeks plus daily oral clodronate. All patients who have reached plateau phase on these regimens are randomised into part B of the trial. Maintenance therapy with alpha-2-interferon versus no maintenance therapy.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
clodronate

Primary outcome measure
Not provided at time of registration.

Secondary outcome measures
Not provided at time of registration.

Overall study start date
01/06/1986

Completion date
01/06/1991

Eligibility

Key inclusion criteria
1. Aged <75 years
2. Myelomatosis defined as having at least two of the following:
a. Bone marrow smears or sections showing the presence of a neoplastic plasma cell infiltrate and/or microplasmacytomas
b. A paraprotein present in the blood or urine
c. Definite lytic bone lesions
2. Patients with equivocal myelomatosis are not eligible
3. No previous cytotoxic chemotherapy, except in the circumstances defined in the protocol
4. Able to tolerate a daily fluid intake of not less than 3 L
5. No contraindications to any of the treatment protocols

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration.

Key exclusion criteria
Not provided at time of registration.

Date of first enrolment
01/06/1986

Date of final enrolment
01/06/1991

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
London
United Kingdom
W1B 1AL
+44 (0)20 7636 5422
clinical.trial@headoffice.mrc.ac.uk

Sponsor type
Research council

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

Funder(s)

Funder type
Government

Funder Name
UK Medical Research Council

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	01/06/2001		Yes	No