MYELOMA VIIIth trial

Submission date	Recruitment status	Prospectively registered
25/10/2000	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
25/10/2000	Completed	Results
Last Edited	Condition category	Individual participant data
27/09/2019	Cancer	[] Record updated in last year

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

G8003737 expired Oct 99

Study information

Scientific Title

MYELOMA VIIIth trial

Acronym

MYELOMA VIIIth trial

Study objectives

To compare, for survival, the induction of first plateau phase in previously untreated patients with multiple myeloma, the efficacy of the above two treatments

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)

Other

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Leukaemia

Interventions

All patients receive three courses of ABCM. They are then randomised to continue with ABCM or to change to oral weekly cyclophosphamide.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Cyclophosphamide and ABCM

Primary outcome measure

- 1. Survival
- 2. Obtaining plateau (stable disease with no more than minimal symptoms)
- 3. Quality of life

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/11/1993

Completion date

01/11/2000

Eligibility

Key inclusion criteria

- 1. Greater than 65 years old and less than 75 years old
- 2. Myeloma
- 3. No previous cytotoxic therapy
- 4. Netrophil count greater than or equal to $1.3 \times 10^9/l$
- 5. Platelet count greater than or equal to $75 \times 10^9/L$
- 6. Able to tolerate 3 l of fluid per day
- 7. Apyrexial
- 8. Free from infection
- 9. Informed consent

Participant type(s)

Patient

Age group

Senior

Sex

Not Specified

Target number of participants

1000

Key exclusion criteria

Patients with equivocal myelomatosis

Date of first enrolment

01/11/1993

Date of final enrolment

01/11/2000

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Department of Immunology
Birmingham
United Kingdom
B15 2TT

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

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