

# MYELOMA VIIIth trial

<b>Submission date</b> 25/10/2000	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/10/2000	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 27/09/2019	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Mark Drayson

### Contact details

Department of Immunology  
Medical School  
University of Birmingham  
Vincent Drive  
Birmingham  
United Kingdom  
B15 2TT

-

m.t.drayson@bham.ac.uk

## 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. Neutrophil 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