# 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

Dr ICM MacLennan

#### Contact details

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# Additional identifiers

EudraCT/CTIS number

**IRAS** number

ClinicalTrials.gov number

**Secondary identifying numbers** 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

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Not specified

#### Study type(s)

**Not Specified** 

#### Participant information sheet

#### 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 measure

Not provided at time of registration

#### Secondary outcome measures

Not provided at time of registration

#### Overall study start date

01/11/1993

#### 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** 

#### Age group

Adult

#### 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

# Date of final enrolment 31/12/2002

# Locations

#### Countries of recruitment

England

**United Kingdom** 

Study participating centre University of Birmingham 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

#### **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