Medical Research Council/ European Blood and Marrow Transplant Prospective Randomised Trial of Autograft in Chronic Myeloid Leukaemia (CML)

Submission date	Recruitment status	Prospectively registered
19/08/2002	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
19/08/2002	Stopped	Results
Last Edited	Condition category	[] Individual participant data
26/03/2020	Cancer	 Record updated in last year

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

Study information

Scientific Title

Medical Research Council/ European Blood and Marrow Transplant Prospective Randomised Trial of Autograft in Chronic Myeloid Leukaemia (CML)

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)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Leukaemia (chronic)

Interventions

Two Arms:

- 1. Control: Interferon (IFN) Starting dose $3 \times 10(6)$ units $\times 3$ /week escalating to $5 \times 10(6)$ units/m (2) daily. Adjusted to maintain leukocyte count 2-4 $\times 10(9)$ /l. Use of hydroxyurea and/or ara-c optional.
- 2. Investigational: Mobilised or straight autograft, followed by IFN (+/- Ara-c).

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Not provided at time of registration.

Secondary outcome measures

Not provided at time of registration.

Overall study start date

01/10/1996

Completion date

30/10/2001

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

- 1. Newly diagnosed Ph-positive and/or breakpoint cluster region (BCR)-abelson (ABL) positive CML
- 2. Aged 15-65
- 3. Chronic phase disease
- 4. No contraindication to the collection of peripheral blood progenitor cells before commencing treatment
- 5. No major organ impairment
- 6. No pregnancy

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Not provided at time of registration.

Key exclusion criteria

Not provided at time of registration.

Date of first enrolment

01/10/1996

Date of final enrolment

30/10/2001

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

Not defined

Funder Name

European Bone Marrow Transplantation Group

Funder Name

Medical Research Council (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