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

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 19/08/2002	**Overall study status** Stopped	[_] Statistical analysis plan [_] Results
Last Edited 26/03/2020	**Condition category** Cancer	[_] Individual participant data [_] 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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

MRC CML 2000 (IVa)

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 x 10(6) units x 3/week escalating to 5 x 10(6) units/m (2) daily. Adjusted to maintain leukocyte count 2-4 x 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
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United Kingdom
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+44 (0)20 7636 5422
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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