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CML IV - Chronic phase chronic myeloid leukaemia/CML 2000

Submission date 25/10/2000	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 25/10/2000	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 15/08/2012	**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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G8223452

Study information

Scientific Title

Acronym
CML 2000

Study objectives
To improve on the best current therapy in chronic phase CML for patients who do not undergo allogeneic BMT with respect to prolonging survival. The trial will compare the combination of a cycle of chemotherapy and an autograft with subsequent alpha IFN with alpha IFN therapy alone. Also, to compare whether low dose alpha IFN therapy is as effective as high dose alpha IFN therapy.

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)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Leukaemia

Interventions
Cycle of chemotherapy and an autograft with subsequent IFN/IFN therapy alone

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Length of survival, quality of life, cytogenetic response

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1996

Completion date
31/10/2001

Eligibility

Key inclusion criteria
1. The interval from diagnosis to registration does not exceed 3 months (if received only hydroxyurea in these 3 months proceed to register, if alpha Interferon (IFN) has been given contact co-ordinators)
2. They are aged 18-60; they have newly diagnosed CML
3. They have acceptable criteria for chronic phase
4. They have given informed consent and are willing to be randomised, there is no contraindication to collection of blood or marrow progenitor cells before treatment is commenced
5. They are not pregnant

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Not Specified

Target number of participants
800

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/1996

Date of final enrolment

31/10/2001

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Academic Transfusion Medicine Unit, Cancer Division
Glasgow
United Kingdom
G31 2ER

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
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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