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CML IV - Chronic phase chronic myeloid leukaemia/CML 2000

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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
Length of survival, quality of life, cytogenetic response

Key secondary outcome(s)
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Not Specified

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
United Kingdom

Scotland

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

Sponsor information

Organisation
Medical Research Council (MRC) (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, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration