

CML IV - Chronic phase chronic myeloid leukaemia/CML 2000

Submission date 25/10/2000	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 25/10/2000	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 15/08/2012	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Study design

Randomised controlled trial

Primary study design

Interventional

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