

CML V - chronic phase Chronic Myeloid Leukaemia

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 checked="" type="checkbox"/> Results
Last Edited 07/08/2009	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr P Shepherd

Contact details
Department of Haematology
Western General Hospital
Edinburgh
United Kingdom
EH4 2XU

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00002869

Secondary identifying numbers
G8223452

Study information

Scientific Title

Study objectives

To determine whether there is any significant difference between the duration of chronic phase and overall survival in patients given low-dose alpha IFN, to study toxicity profiles in the two arms of the trial as assessed by WHO criteria and by percentage of patients requiring dose reduction or abandoning therapy because of side effects, to study haematologic and cytogenetic response at six monthly intervals on treatment with either low-dose or high-dose alpha IFN.

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

Interventions

High/low-dose Interferon (IFN).

Optional use of arm-C in addition to randomised IFN therapy.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Overall survival
2. Frequency of haematologic and cytogenetic response
3. Duration of chronic phase and overall survival

- 4. Toxicity profiles
- 5. Side effects
- 6. Performance status
- 7. Quality of life

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/04/1995

Completion date

01/01/2002

Eligibility

Key inclusion criteria

1. Newly diagnosed, previously untreated CML in chronic phase (therapeutic or back up leucapheresis does not preclude entry to the trial. Patients may be started on hydroxyurea for up to 4 weeks before randomisation)
2. The presence of the Ph chromosome or molecular evidence of Breakpoint Cluster Region (BCR)/Abelson (ABL) re-arrangement
3. World Health Organisation (WHO) performance status is 0./1, or 2
4. There is informed consent in accordance with MRC requirements and that of local ethics committees
5. Adequate hepatic and renal functions defined by bilirubin and creatinine levels below twice the upper limit. The possibility of allogeneic Bone Marrow Transplant (BMT) does not preclude entry to the trial

Participant type(s)

Patient

Age group

Not Specified

Sex

Both

Target number of participants

800

Key exclusion criteria

1. Received previous treatment for CML
2. WHO performance status 3 or 4
3. Accelerated phase or established blast crisis; severe concurrent hepatic, renal or cardiovascular problems or a history of severe depression in the past
4. Pregnancy

Date of first enrolment

01/04/1995

Date of final enrolment

01/01/2002

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre

Department of Haematology

Edinburgh

United Kingdom

EH4 2XU

Sponsor information

Organisation

University of Oxford (UK)

Sponsor details

University Offices

Wellington Square

Oxford

England

United Kingdom

OX1 2JD

+44 (0)1865 270000

research.services@admin.ox.ac.uk

Sponsor type

University/education

Website

<http://www.ox.ac.uk/>

ROR

<https://ror.org/052gg0110>

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/06/2004		Yes	No