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CML V - chronic phase Chronic Myeloid Leukaemia

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	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/08/2009	Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00002869

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

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

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

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 cardio-vascular 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
United Kingdom

Scotland

Study participating centre

Department of Haematology
Edinburgh
United Kingdom
EH4 2XU

Sponsor information

Organisation
University of Oxford (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

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