

# CML V - chronic phase Chronic Myeloid Leukaemia

<b>Submission date</b> 25/10/2000	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 25/10/2000	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/08/2009	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**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

**Primary study design**

Interventional

**Study design**

Randomised controlled trial

**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 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

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, 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

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	15/06/2004		Yes	No