# Trial of alpha-interferon in chronic myeloid leukaemia and a comparison of busulphan and hydroxyurea for induction and maintenance

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
19/08/2002		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
19/08/2002	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
15/11/2019	Cancer			

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

#### Contact name

Dr - -

#### Contact details

UKCCCR Register Co-ordinator MRC Clinical Trials Unit 222 Euston Road London United Kingdom NW1 2DA

#### Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

CML IIIB

# Study information

#### Scientific Title

Trial of alpha-interferon in chronic myeloid leukaemia and a comparison of busulphan and hydroxyurea for induction and maintenance

#### **Study objectives**

Not provided at time of registration.

#### 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 (chronic)

#### **Interventions**

There are four treatment arms, clinicians may choose to randomise between only arms 1 and 2, 3 and 4, 2 and 4 or to randomise between all treatment arms.

- 1. Regimen A: Induction therapy with busulphan followed by maintenance therapy with busulphan plus alpha-interferon.
- 2. Regimen B: Induction therapy with busulphan followed by maintenance therapy with busulphan only.
- 3. Regimen C: Induction therapy with hydroxyurea followed by maintenance therapy with hydroxyurea plus alpha-interferon.
- 4. Regimen D: Induction therapy with hydroxyurea followed by maintenance therapy with hydroxyurea only.

#### **Intervention Type**

Drug

#### Phase

**Not Specified** 

#### Drug/device/biological/vaccine name(s)

Alpha-Interferon, busulphan, hydroxyurea

#### Primary outcome measure

Not provided at time of registration.

#### Secondary outcome measures

Not provided at time of registration.

#### Overall study start date

01/08/2000

#### Completion date

01/08/2005

# **Eligibility**

#### Key inclusion criteria

- 1. Aged over 75 years with either Ph positive or Ph negative chronic myeloid leukaemia in chronic phase. Patients over 75 years or patients unwilling to accept alpha-interferon, may be randomised to busulphan or hydroxyurea, but not interferon or no interferon
- 2. Adequate renal function
- 3. No severe concurrent hepatic, renal, cardiovascular, organic brain disease or psychiatric illness
- 4. Patients with established blast cell crisis or extramedullary granulocytic sarcomas are to be excluded
- 5. Patients with accelerated phase or platelet count below that specified in the protocol are not eligible

#### Participant type(s)

**Patient** 

#### Age group

Senior

#### Sex

**Not Specified** 

#### Target number of participants

Not provided at time of registration.

#### Total final enrolment

587

#### Key exclusion criteria

Not provided at time of registration.

#### Date of first enrolment

01/08/2000

# Date of final enrolment 01/08/2005

#### Locations

#### Countries of recruitment

England

**United Kingdom** 

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

# Sponsor information

#### Organisation

Medical Research Council (MRC) (UK)

#### Sponsor details

20 Park Crescent London United Kingdom W1B 1AL +44 (0)20 7636 5422 clinical.trial@headoffice.mrc.ac.uk

#### Sponsor type

Research council

#### Website

http://www.mrc.ac.uk

# Funder(s)

#### Funder type

Government

#### Funder Name

UK Medical Research Council

### **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	03/06/1995	15/11/2019	Yes	No