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

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