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A pilot study of continuous imatinib mesylate (IM) versus pulsed imatinib with or without lenograstim (recombinant human granulocyte colony stimulating factor [rHu-GCSF]) in chronic myeloid leukaemia (CML) patients who have achieved a complete cytogenetic response

Submission date 05/07/2004	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol
Registration date 05/07/2004	**Overall study status** Completed	[ ] Statistical analysis plan [X] Results
Last Edited 25/10/2022	**Condition category** Cancer	[ ] Individual participant data

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-different-ways-of-giving-glivec-to-people-with-cml

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2004-000179-33

Protocol serial number
LRF 03/101

Study information

Scientific Title
A pilot randomised controlled study of continuous imatinib mesylate (IM) versus pulsed imatinib with or without lenograstim (recombinant human granulocyte colony stimulating factor [rHu-GCSF]) in chronic myeloid leukaemia (CML) patients who have achieved a complete cytogenetic response

Acronym
GIMI

Study objectives
Continuous imatinib mesylate (IM) versus pulsed imatinib with or without lenograstim (recombinant human granulocyte colony stimulating factor [rHu-GCSF]) in chronic myeloid leukaemia (CML) patients who have achieved a complete cytogenetic response.

This trial is also listed in the the UK Clinical Research Network Study Portfolio: http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=1451

Ethics approval required
Old ethics approval format

Ethics approval(s)
Multicentre research ethics committee (MREC) Scotland approved on the 16th September 2004 (MREC ref: 04/MRE00/52)

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic myeloid leukaemia (CML)

Interventions
Patients who are in complete cytogenetic remission for at least 6 months subsequent to IM therapy will be randomised to receive either pulsed IM, pulsed IM with G-CSF, or continuous IM.

Total duration of treatment: 12 months
Total duration of follow-up: 4 years

Intervention Type
Other

Phase
Phase IV

Primary outcome(s)
Added 06/01/2010:
1. Safety of combination GCSF and imatinib
2. Safety of pulsed imatinib arms

Endpoints measured at end of last recruited patient 12 month treatment (September 2007) and then 4 years after this timepoint (September 2011).

Key secondary outcome(s)
Added 06/01/2010:
1. Molecular response to imatinib interruption
2. Proportion of patients progressing

Endpoints measured at end of last recruited patient 12 month treatment (September 2007) and then 4 years after this timepoint (September 2011).

Completion date
10/10/2006

Eligibility

Key inclusion criteria
1. Aged greater than or equal to 18 years, either sex
2. Patients, who having been established on IM therapy at the appropriate licensed dose, have maintained a complete cytogenetic response for at least 6 months (confirmed on bone marrow [BM] performed within 3 months of study entry)
3. Patients who remain quantitative reverse transcription polymerase chain reaction (Q-RT-PCR) positive and have a peripheral blood (PB) Q-RT-PCR breakpoint cluster region-Abelson (BCR-ABL) /ABL ratio of less than 2% (within 4 weeks of study entry)
4. All chronic Phase patients, with criteria as follows:
4.1. Less than 10% blasts in peripheral blood (PB) or bone marrow (BM)
4.2. Less than 30% blasts plus promyelocytes in PB or BM
4.3. Less than 20% blasts in PB
5. Acute phase (AP) patients only if their definition of AP was based on karyotypic evolution on BM cytogenetics as an isolated feature of progression
6. Written voluntary informed consent

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
45

Key exclusion criteria
1. Patients with serum bilirubin, aspartate aminotransferase (AST), alanine aminotransferase (ALT) or creatinine concentration greater than 2 times the institutional upper limit of the normal range
2. Patients who have evidence of extramedullary disease
3. Treatment with investigational drugs within 28 days of study entry
4. Patients with uncontrolled medical disease such as diabetes mellitus, thyroid dysfunction, neuropsychiatric disorders, infection, angina or Grade 3 - 4 cardiac problems as defined by the New York Heart Association Criteria
5. Patients who have undergone major surgery within 4 weeks of study day 1, or who have not recovered from prior major surgery
6. Patients who are: pregnant, breast feeding, of childbearing potential without a negative pregnancy test prior to study entry or who are unwilling to use barrier contraception throughout the trial and for 3 months after cessation of therapy (postmenopausal women must be amenorrhoeic for at least 12 months to be considered of non-childbearing potential)
7. Patients with a history of non-compliance to medical regimens or who are considered potentially unreliable

Date of first enrolment
10/10/2004

Date of final enrolment
10/10/2006

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre

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Sponsor information

Organisation
Leukaemia Research Fund (UK)

ROR
https://ror.org/0055acf80

Funder(s)

Funder type
Charity

Funder Name
Leukaemia Research Fund (UK)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	01/06/2009		Yes	No
Plain English results			25/10/2022	No	Yes