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Mini-allografting to complement treatment with glivec (Imatinib - formerly known as STI571) to eradicate minimal residual disease (MRD) in chronic myeloid leukaemia (CML) patients aged 65 years and under with matched sibling donors

Submission date	Recruitment status	[_] Prospectively registered
30/09/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/04/2018	Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0436130285

Study information

Scientific Title
Mini-allografting to complement treatment with glivec (Imatinib - formerly known as STI571) to eradicate minimal residual disease (MRD) in chronic myeloid leukaemia (CML) patients aged 65 years and under with matched sibling donors: a randomised controlled trial

Study objectives
To develop a novel clinical immune-therapeutic strategy for CML patients aged 65 and under, found to have suitable matched sibling allogeneic donors, and following remission induction with Glivec.

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)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions

Patients will be given imatinib for 6 - 12 months with dose increases to 600 mg for poor response. Reduced intensity allograft with peripheral blood stem cells (PBSC) after fludarabine, melphelan and campath conditioning will then take place. If the patient is less than 55 years and there is no complete cytogenetic response (CCR) by the end of 12 months of imatinib despite the dose increase to 600 mg, and if the patient is fit and well, there is an option for total body irradiation (TBI) and cyclophosphamide followed by bone marrow transplantation (BMT).

Stem cell transplantation (SCT) followed by incremental donor lymphocyte infusions (DLI) starting with 5 x 10^5 T cells/kg every 12 weeks from six months after allograft until the patient is in complete molecular remission by quantitative reverse transcription polymerase chain reaction (Q-RT-PCR). If the patient requires anti-leukaemic therapy prior to six months following SCT or if graft versus host disease (GVHD) prevents DLI after six months then there is an option for further imatinib post-SCT.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Survival and remission status at six months and one year post-transplant.

Secondary outcome measures
Not provided at time of registration

Overall study start date
30/11/2002

Completion date
30/09/2005

Eligibility

Key inclusion criteria
1. Patients aged 65 years and under
2. A diagnosis of chronic myeloid leukaemia
3. Attending the Haematology Out-patients' clinic
4. Fulfill the eligibility criteria

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

Key exclusion criteria
Does not comply with the above inclusion criteria

Date of first enrolment
30/11/2002

Date of final enrolment
30/09/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leeds Teaching Hospitals NHS Trust
Leeds
United Kingdom
LS1 3EX

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Leeds Teaching Hospitals NHS Trust (UK)

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	15/05/2008		Yes	No