

# 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

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 26/04/2018	<b>Condition category</b> Cancer	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr G M Smith

**Contact details**  
Haematological Oncology Department  
D Floor, Brotherton Wing  
Leeds Teaching Hospitals NHS Trust  
Great George Street  
Leeds  
United Kingdom  
LS1 3EX  
+44 (0)113 392 5153  
graeme.smith@leedsth.nhs.uk

## Additional identifiers

**Protocol serial number**

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

**Study type(s)**

Treatment

**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  $5 \times 10^5$  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(s)**

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

**Key secondary outcome(s)**

Not provided at time of registration

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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**

United Kingdom

England

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

## Sponsor information

**Organisation**  
Department of Health

## Funder(s)

**Funder type**  
Government

**Funder Name**  
Leeds Teaching Hospitals NHS Trust (UK)

## 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	15/05/2008		Yes	No