

# A pilot study to assess the efficacy and safety of dasatinib after allogeneic stem cell transplantation in patients with de novo Philadelphia positive (bcr-abl+) acute lymphoblastic leukemia

<b>Submission date</b> 25/10/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 04/11/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 04/11/2010	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**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

DASA-TRAS

# Study information

## Scientific Title

Multicenter, non-randomised Phase II pilot study to assess the efficacy and safety of dasatinib after allogeneic stem cell transplantation in patients with de novo Philadelphia positive (bcr-abl +) acute lymphoblastic leukemia

## Acronym

DASA-TRAS

## Study objectives

Treatment with dasatinib 100 mg daily (QD) is safe and efficacious when given to patients with Philadelphia chromosome positive (Ph+) Acute Lymphoblastic Leukaemia (ALL) in the post Stem Cell Transplantation (SCT) setting

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

The local ethics committee (Comité Ético Investigación Clínica [CEIC], Hospital La Fe) approved on the 19th of December 2009

## Study design

Multicentre pilot single arm open label Phase II study

## Primary study design

Interventional

## Secondary study design

Non randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

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

## Health condition(s) or problem(s) studied

Acute lymphoblastic leukaemia (ALL); Philadelphia chromosome positive (Ph+)/BCR-ABL+

## Interventions

Treatment with 100 mg QD of dasatinib (Sprycel) administered orally as continuous daily dosing (CDD)

**Intervention Type**

Other

**Phase**

Phase II

**Primary outcome measure**

Disease Free Survival (DFS) at 2 years

**Secondary outcome measures**

1. Duration of hematologic, cytogenetic and molecular remission
2. Relapse rate at 2 years
3. Survival at 2 years
4. Overall DFS
5. Overall Survival (OS)

**Overall study start date**

08/04/2010

**Completion date**

08/04/2014

**Eligibility****Key inclusion criteria**

1. Adult patients  $\geq 18$  years
2. Diagnostic confirmation of de novo Ph+ (BCL-ABL translocation) ALL
3. Patients in first/second complete remission (CR) (assessed by cytology, karyotyping, fluorescent in-situ hybridisation [FISH] and BCR/ABL reverse transcriptase- polymerase chain reaction [RT-PCR]) at transplantation
4. Patients with sustained hematologic and cytogenetic CR at the time of study entry
5. Any modality of allogeneic SCT
6. Patients are in day +180 ( $\pm 2$  weeks) after allogeneic SCT with stable graft (patients may sign informed consent from day +166 on, but will not start study treatment until they have reached day +180 and not later than day + 194)
7. Ability to understand and voluntarily sign the informed consent form
8. Women of childbearing potential (WOCBP) must be using an adequate method of contraception to avoid pregnancy and have a negative pregnancy test, a maximum of 48 hours prior to study drug start

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

### **Target number of participants**

30 Patients

### **Key exclusion criteria**

1. Patients with Eastern Cooperative Oncology Group (ECOG) 3-4 at study entry
2. Any of the following laboratory abnormalities:
  - 2.1. Absolute neutrophil count  $< 1.5 \times 10^9/l$  or platelets  $< 75 \times 10^9/l$
  - 2.2. Serum creatinine  $> 2.0 \text{ mg/dl}$  ( $177 \text{ mmol/l}$ )
  - 2.3. Serum glutamic oxalacetic transaminase (SGOT) or serum glutamate pyruvate transaminase (SGPT)  $> 5.0 \times$  upper limit of normal (ULN)
  - 2.4. Total bilirubin  $> 3 \text{ mg/dl}$
3. Known HIV infection or any other uncontrolled infection at study entry
4. Known pleural effusion of any grade at study entry
5. Morphologic or cytogenetic or molecular relapse at study entry
6. Evidence of digestive dysfunction that could prevent administration of study therapy
7. Prior therapy with dasatinib
8. Other concurrent malignancy at study entry
9. Uncontrolled or significant cardiovascular disease, including myocardial infarction within 6 months, uncontrolled angina within 3 months, prolonged QT interval, congestive heart failure within 3 months and clinically significant ventricular arrhythmias
10. Any psychiatric condition that could prevent patient from signing the informed consent or could put the patient at an unacceptable risk in case of participating in the trial
11. Subjects enrolled in another clinical trial at study entry. If patients have received other investigational agent, a minimum of 30 days wash-out period must have elapsed.

### **Date of first enrolment**

08/04/2010

### **Date of final enrolment**

08/04/2014

## **Locations**

### **Countries of recruitment**

Spain

### **Study participating centre**

Hospital la Fe

Valencia

Spain

46009

## **Sponsor information**

**Organisation**

Spanish Group of Hematopoietic Transplantation and Cell Therapy (GETH) (Spain)

**Sponsor details**

C/ Fortuna, nº 51, local 5  
Madrid  
Spain  
28010

**Sponsor type**

Research organisation

**ROR**

<https://ror.org/015xc6321>

**Funder(s)****Funder type**

Research organisation

**Funder Name**

Spanish Group of Hematopoietic Transplantation and Cell Therapy (Grupo Español de Transplantes Hematopoyéticos y Terapia celular [GETH]) (Spain)

**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