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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

Submission date 25/10/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 04/11/2010	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 04/11/2010	**Condition category** Cancer	[ ] Individual participant data [ ] 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 ≥ 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 (± 2 weeks) after allogeneic SCT with stable graft (patients may sign inform 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 x 109/l or platelets < 75 x 109/l
2.2. Serum creatinine > 2.0 mg/dl (177 mmol/l)
2.3. Serum glutamic oxalacetic transaminase (SGOT) or serum glutamate piruvate transaminase (SGPT) > 5,0 x upper limit of normal (ULN)
2.4. Total bilirrubin > 3 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