

Autologous Stem cell Transplantation International Scleroderma (ASTIS) trial

Submission date 21/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 19/10/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/07/2014	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

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
NTR338

Study information

Scientific Title

High dose immunoablation and autologous haematopoietic stem cell transplantation versus monthly intravenous pulse therapy

Acronym

ASTIS

Study objectives

It is postulated that high dose immunoablation and autologous stem cell transplantation has superior clinical benefit in comparison to intravenous pulse therapy cyclophosphamide, with respect to survival and prevention of major organ failure (referred to as event-free survival which is considered the primary endpoint) and has a greater impact on skin thickening, visceral involvement, functional status and quality of life.

On 17/04/2012 the following changes were made to the trial record:

1. Australia has been removed from the countries of recruitment and Belgium added.
2. The target number of participants has been changed from 200 to 156.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Multicentre randomised active-controlled parallel-group 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 below to request a patient information sheet

Health condition(s) or problem(s) studied

Systemic sclerosis

Interventions

This multicentre prospective randomised controlled phase III study compares efficacy and safety of high dose immunoablation and autologous haematopoietic stem cell transplantation (HSCT) (considered the investigational treatment), versus monthly intravenous pulse-therapy cyclophosphamide (considered the control treatment). The investigational treatment arm comprises the following consecutive steps:

1. Mobilisation of haematopoietic stem cells with intravenous (IV) cyclophosphamide ($2 \times 2 \text{ g/m}^2$) and filgrastim (10 mg/kg/day)
2. Leukapheresis and selection of CD34+ stem cells
3. Conditioning with IV cyclophosphamide (200 mg/kg) and rbATG (7.5 mg/kg)
4. HSCT

The procedures are normally completed within three to four months after randomisation.

The control treatment arm consists of 12 consecutive monthly IV pulses cyclophosphamide (750 mg/m^2).

As of 17/04/2012, the sponsor name has been amended from European Group Bone Marrow + Transplantation (EBMT)/European League Against Rheumatism (EULAR) Working Party Autoimmune Diseases to European Group for Bone Marrow Transplantation.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Cyclophosphamide, filgrastim, rabbit Anti-Thymocyte Globulin (rbATG)

Primary outcome measure

Current primary outcome measure(s) as of 29/05/2012

The primary endpoint is event-free survival defined as the time in days from the day of randomisation until the occurrence of death or the development of persistent major organ failure (heart, lung, kidney).

Previous primary outcome measure(s)

The primary endpoint is event-free survival defined as the time in days from the day of randomisation until the occurrence of death or the development of persistent major organ failure (heart, lung, kidney) during the study period of two years.

Secondary outcome measures

Key secondary outcomes include:

1. Treatment related mortality
2. Treatment toxicity
3. Progression-free survival

Overall study start date

22/03/2001

Completion date

01/01/2008

Eligibility

Key inclusion criteria

Patients with diffuse systemic sclerosis, aged 16 to 65 years, and:

1. Disease duration four years or less, plus evidence of heart, lung or kidney involvement, plus skin score of 15 or more, or
2. Disease duration two years or less, plus evidence of an acute phase reaction in blood, plus skin score 20 or more

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

156

Key exclusion criteria

Patients with concomitant severe disease, extensive pretreatment according to predefined criteria with cyclophosphamide are excluded.

Date of first enrolment

22/03/2001

Date of final enrolment

01/01/2008

Locations

Countries of recruitment

Austria

Belgium

Canada

England

France

Germany

Greece

Italy

Netherlands

Switzerland

United Kingdom

Study participating centre
Institute of Cellular Medicine,
Newcastle upon Tyne
United Kingdom
NE2 4HH

Sponsor information

Organisation

European Group for Bone Marrow Transplantation

Sponsor details

EBMT Central Office
Dept. Haematology
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W1N 8AA
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Sponsor type

Other

Website

<http://www.ebmt.org>

Funder(s)

Funder type

Industry

Funder Name

European League Against Rheumatism (EULAR)

Funder Name

Amgen Europe

Funder Name

Sangstat B.V. (The Netherlands)

Funder Name

Horton Foundation (Switzerland)

Funder Name

AP - HP

Alternative Name(s)

Assistance Publique Hôpitaux de Paris, Assistance Publique–Hôpitaux de Paris, AP-HP

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

France

Funder Name

European Group for Blood and Marrow Transplantation (EBMT)

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?
Protocol article	protocol	01/10/2005		Yes	No
Results article	results	25/06/2014		Yes	No