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A multi-centre, phase II-III randomised clinical trial and observational study of defibrotide for the treatment of hepatic veno-occlusive disease after stem cell transplant

Submission date
12/09/2003

Registration date
12/09/2003

Last Edited
22/04/2015

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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

N0231120099

Study information

Scientific Title
A multi-centre, phase II-III randomised clinical trial and observational study of defibrotide for the treatment of hepatic veno-occlusive disease after stem cell transplant

Study objectives
Test the efficacy of defibrotide in the survival of patients for whom a diagnosis of veno-occlusive disease (VOD) is formulated and documented according to well predefined criteria.

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

Health condition(s) or problem(s) studied
Hepatic veno-occlusive disease (VOD)

Interventions
Randomised phase II-III multi-centre study of defibrotide in hepatic veno-occlusive disease after stem cell transplant.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Defibrotide

Primary outcome measure
Survival at 7, 14, 30, 60 and 100 days after diagnosis.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/02/2003

Completion date
01/02/2005

Eligibility

Key inclusion criteria
All patients with diagnosis of VOD after a stem cell transplant.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/02/2003

Date of final enrolment
01/02/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Southampton General Hospital
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
Department of Health (UK)

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

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Southampton University 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