ISRCTN65464501 https://doi.org/10.1186/ISRCTN65464501

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

Contact name
Dr Kim Orchard

Contact details
Haematology Department, MP 8
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
Survival at 7, 14, 30, 60 and 100 days after diagnosis.

Key secondary outcome(s)
Not provided at time of registration

Completion date
01/02/2005

Eligibility

Key inclusion criteria

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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

Study participating centre
Southampton General Hospital
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
Southampton University Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration