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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

**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

### Study design
Randomised controlled trial

### Primary study design
Interventional

### 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