

# 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

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 22/04/2015	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

**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