

# The Drainage, Irrigation and Fibrinolytic Trial for post-haemorrhagic hydrocephalus in newborn infants

|  |   |   |
|--|---|---|
| <b>Submission date</b><br>01/09/2005   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>08/09/2005 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>23/07/2020       | <b>Condition category</b><br>Neonatal Diseases    | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://www.neonatalneurology.org.uk>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N/A

## **Study information**

### **Scientific Title**

The Drainage, Irrigation and Fibrinolytic Trial for post-haemorrhagic hydrocephalus in newborn infants: a randomised controlled trial

### **Acronym**

DRIFT

### **Study objectives**

In infants with post-haemorrhagic ventricular dilatation, treatment by drainage, irrigation and fibrinolytic therapy reduces ventriculoperitoneal shunt surgery and disability at 2 years when compared to best standard therapy.

On 11/02/2009 the following changes were made to the trial record:

1. The overall trial start date was changed from 28/02/2003 to 01/02/2003.
2. The overall trial end date was changed from 30/06/2009 to 28/02/2009.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Southmead Local Research Ethics Committee, 28/01/2003, ref: 134/02

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Not specified

### **Study type(s)**

Treatment

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Post-haemorrhagic ventricular dilatation

### **Interventions**

Drainage, irrigation and fibrinolytic therapy versus best standard therapy

## **Intervention Type**

Mixed

## **Primary outcome measure**

1. Ventriculoperitoneal shunt surgery
2. Disability at 2 years post-term

## **Secondary outcome measures**

1. Secondary haemorrhage
2. Secondary central nervous system (CNS) infection
3. Death before 2 years post-term
4. Hospital admissions by 2 years of age

## **Overall study start date**

01/02/2003

## **Completion date**

28/02/2009

# **Eligibility**

## **Key inclusion criteria**

1. Infants of less than 28 days of age
2. Intraventricular haemorrhage
3. Progressive enlargement of ventricles to 4 mm over the 97th centile for width or 1 mm over the 97th centile for diagonal, thalamo-occipital and third ventricle or enlargement of one ventricle together with midline shift

## **Participant type(s)**

Patient

## **Age group**

Neonate

## **Sex**

Both

## **Target number of participants**

120

## **Total final enrolment**

77

## **Key exclusion criteria**

Generalised bleeding tendency

## **Date of first enrolment**

01/02/2003

**Date of final enrolment**

31/12/2006

**Locations****Countries of recruitment**

England

Norway

Poland

United Kingdom

**Study participating centre**

University of Bristol Medical School

Bristol

United Kingdom

BS10 5NB

**Sponsor information****Organisation**

North Bristol NHS Trust (UK)

**Sponsor details**

Frenchay Hospital

Bristol

England

United Kingdom

BS16 1LE

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annette.clarke@nbt.nhs.uk

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/036x6gt55>

**Funder(s)****Funder type**

Charity

**Funder Name**

Cerebra (UK)

**Alternative Name(s)****Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United Kingdom

**Funder Name**

James and Grace Anderson 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

**Study outputs**

| Output type                        | Details                   | Date created | Date added | Peer reviewed? | Patient-facing? |
|------------------------------------|---------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>    | phase I trial results     | 01/04/2003   |            | Yes            | No              |
| <a href="#">Other publications</a> | short term outcomes       | 01/05/2007   |            | Yes            | No              |
| <a href="#">Results article</a>    | results                   | 01/04/2010   |            | Yes            | No              |
| <a href="#">Results article</a>    | results                   | 01/02/2019   |            | Yes            | No              |
| <a href="#">Results article</a>    | 10-year follow up results | 04/07/2020   | 23/07/2020 | Yes            | No              |