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

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|---|---|---|
| **Submission date**<br>01/09/2005 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>08/09/2005 | **Overall study status**<br>Completed | |
| **Last Edited**<br>23/07/2020 | **Condition category**<br>Neonatal Diseases | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

## 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

### Primary study design
Interventional

### Study design
Randomised controlled trial

### Study type(s)
Treatment

### 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(s)
1. Ventriculoperitoneal shunt surgery
2. Disability at 2 years post-term

### Key secondary outcome(s)
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

### 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 diagnonal, thalamo-occipital and third ventricle or enlargement of one ventricle together with midline shift

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Neonate

### Sex
All

### 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
United Kingdom

England

Norway

Poland

### Study participating centre
**University of Bristol Medical School**
Bristol
United Kingdom
BS10 5NB

# Sponsor information

**Organisation**
North Bristol NHS Trust (UK)

**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

**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? |
|---|---|---|---|---|---|

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|---|---|---|---|---|---|
| Results article | phase I trial results | 01/04/2003 | | Yes | No |
| Results article | results | 01/04/2010 | | Yes | No |
| Results article | results | 01/02/2019 | | Yes | No |
| Results article | 10-year follow up results | 04/07/2020 | 23/07/2020 | Yes | No |
| Other publications | short term outcomes | 01/05/2007 | | Yes | No |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |