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

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

Study design
Randomised controlled trial

Primary study design
Interventional

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?

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