

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

Submission date 01/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/07/2020	Condition category 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?
Results article	phase I trial results	01/04/2003		Yes	No
Other publications	short term outcomes	01/05/2007		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