

A pragmatic randomised controlled trial of treatments for Idiopathic Intracranial Hypertension

Submission date 01/04/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/04/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 29/11/2013	Condition category Circulatory System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Carl Clarke

Contact details
Department of Neurology
City Hospital
Dudley Road
Birmingham
United Kingdom
B18 7QH
+44 (0)121 507 4073
c.e.clarke@bham.ac.uk

Additional identifiers

Study information

Scientific Title

Acronym

The IIH Trial

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Idiopathic Intracranial Hypertension

Interventions

1. Acetazolamide
2. Weight reduction
3. Optic nerve sheath fenestration
4. Ventriculo-peritoneal or lumbo-peritoneal shunts

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/05/2002

Eligibility

Key inclusion criteria

1. Diagnosis of Idiopathic Intracranial Hypertension (including that caused by medication such as tetracyclines)
2. Willing to give written informed consent

3. Able to complete trial documentation
4. Randomising clinician is uncertain about the treatment the patient should receive

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

1. Idiopathic; Intracranial Hypertension caused by cerebral venous sinus thrombosis or chronic neurological conditions (e.g. infections)
2. Contraindication to acetazolamide such as hypokalaemia, hyponatraemia, hyperchloraemic acidosis, severe hepatic impairment, renal impairment, sulphonamide sensitivity
3. Randomising clinician is certain about the treatment the patient should receive

Date of first enrolment

01/04/2000

Date of final enrolment

31/05/2002

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Department of Neurology

Birmingham

United Kingdom

B18 7QH

Sponsor information**Organisation**

University of Birmingham (UK)

ROR

<https://ror.org/03angcq70>

Funder(s)

Funder type

Industry

Funder Name

Unrestricted grants from pharmaceutical industry.

Funder Name

Internal research funds.

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	results	01/05/2011		Yes	No