ISRCTN84867253 https://doi.org/10.1186/ISRCTN84867253

A pragmatic randomised controlled trial of treatments for Idiopathic Intracranial Hypertension

Submission date 01/04/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/04/2004	**Overall study status** Completed	
Last Edited 29/11/2013	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

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
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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