

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 <input type="checkbox"/> Protocol
Registration date 23/04/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/11/2013	Condition category Circulatory System	<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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

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 measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/04/2000

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

Age group

Not Specified

Sex

Not Specified

Target number of participants

Not provided at time of registration

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

England

United Kingdom

Study participating centre

Department of Neurology

Birmingham

United Kingdom

B18 7QH

Sponsor information

Organisation

University of Birmingham (UK)

Sponsor details

c/o Department of Pharmacology

University of Birmingham

Medical School

Edgbaston

Birmingham

England

United Kingdom

B15 2TT

+44 (0)121 414 2286

c.mcgarry@bham.ac.uk

Sponsor type

University/education

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

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	results	01/05/2011		Yes	No