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Bariatric surgery versus a community weight loss programme for the sustained treatment of Idiopathic Intracranial Hypertension

Submission date
09/01/2014

Recruitment status
No longer recruiting

Registration date
30/01/2014

Overall study status
Completed

Last Edited
06/07/2022

Condition category
Nervous System Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Idiopathic intracranial hypertension (IIH) is a condition with an unknown cause that is associated with raised pressure in the brain and can cause disabling daily headaches and loss of vision, which can be permanent. The raised brain pressure squashes the nerves supplying the eye (also known as papilloedema) and this can affect vision. Over 90% of patients with IIH are overweight and weight loss is the most effective treatment. Other treatments for IIH have very little current evidence to support their use. This study aims to compare two methods of weight loss, bariatric surgery and the most effective dietary programme commonly available, Weight Watchers, to see which offers the most effective long-term treatment for IIH.

Who can participate?
Women aged between 18 and 55 with IIH and body mass index (BMI) >35kg/m2. Women who do not have IIH are also enrolled for comparison.

What does the study involve?
Participants with IIH are randomly allocated to either attend their local Weight Watchers group or undergo bariatric surgery. The latter are referred to the Birmingham Heartlands Hospital to receive a choice of gastric banding, gastric bypass, or sleeve gastrectomy. A third control group of 20 women with similar characteristics but who do not have IIH provide a comparison but do not participate further in the study. Participants with IIH are then followed up for five years, with the most important measurement being their brain pressure after one year of being in the study. Participants with IIH and the 20 obese controls are also asked to give samples of urine, blood and cerebrospinal fluid, and are asked to participate in sub-studies which look at the relationship between IIH and other illnesses connected with obesity from which they may suffer.

What are the possible benefits and risks of participating?
The benefit is that both groups of participants receive a treatment which is proven to bring about weight loss. The main risk is to patients in the bariatric surgery arm: bariatric surgery, although safe, is a major operation, and careful follow-up is required. Apart from the risks of bariatric surgery for those participants in the surgery arm, the main risks are those of side

effects involved in the lumbar punctures, and the discomfort of the lumbar punctures and of the blood samples being taken.

Where is the study run from?
1. University Hospitals Birmingham (UK)
2. Heartlands Hospital (UK)
3. Royal Devon and Exeter Hospital (UK)
4. Musgrove Park Hospital (UK)
5. Manchester Royal Eye Hospital (UK)

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Mr Ryan Ottridge
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Study website
http://www.birmingham.ac.uk/research/activity/mds/trials/bctu/trials/pd/IIHWT/index.aspx

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02124486

Secondary identifying numbers
RG_12-089

Study information

Scientific Title
A randomised controlled trial of bariatric surgery versus a community weight loss programme for the sustained treatment of Idiopathic Intracranial Hypertension: the IIH:WT Trial

Acronym
IIH:WT

Study objectives
The trial will evaluate the effectiveness of two methods of weight loss in the treatment of IIH: gastric banding vs. dietetic intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Black Country REC, 28/02/2014, ref: 14/WM/0011

Study design
Randomised controlled parallel arm trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Idiopathic Intracranial Hypertension (IIH) - neurology, neuro-ophthalmology.

Interventions
Patients are randomised 1:1 to bariatric surgery or dietetic intervention.

1. 32 participants randomised to the bariatric surgery arm of the trial will be referred to the surgery pathway to receive laparoscopic gastric banding.
2. 32 participants randomised to the dietetic arm will be given vouchers to except them from paying for 12 months of Weight Watchers.

There will also be a 20-participant matched obese control group who will undergo the baseline visit, and a 5-patient magnetic resonance imaging (MRI) test scan group to validate the novel scans being used.

Updated 25/04/2017: sample size increased from 30 to 32 participants in each arm in case of increased dropout.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Change in Intracranial Pressure (ICP) between baseline and 12 months measured by lumbar puncture at baseline and 12 months. ICP will be recorded to the nearest whole number in cmH2O

Secondary outcome measures
Secondary Outcome Measures:
1. Change in ICP between baseline and 24 and 60 months measured by lumbar puncture. ICP will be recorded to the nearest whole number in cmH2O
2. Change in reported IIH symptoms from 0 to 12 months (and at 3, 6, 24 and 60 months) measured by clinician-completed CRFs and participant-completed questionnaire
3. Change in visual function from 0 to 12 months (and at 24 and 60 months). This will be measured by the LogMAR (log of the minimum angle of resolution) chart to assess visual acuity, automated perimetry (Humphrey 24-2 central threshold) to measure the visual field mean deviation, a Pelli-Robson chart to evaluate contrast sensitivity and an Ishihara book to assess colour vision.
4. Change in papilloedema from 0 to 12 months (and at 24 and 60 months). This will be measured using spectral optical coherence tomography. Papilloedema will be further graded by blinded assessment of, and assignation of Frisen score to, fundus photographs.
5. Change in headache-associated disability from 0 to 12 months (and at 24 and 60 months) measured by participant-completed questionnaire including analgesic use, Headache Index, and Headache Impact Test-6
6. Change in anthropological measures (e.g. waist, hip, fat mass) from 0 to 12 months (and at 24 and 60 months)
7. Change in quality of life (participant reported) from 0 to 12 months (and at 24 and 60 months) measured by participant-reported questionnaire (EQ-5D-5L and ICECAP-A questionnaires)
8. Difference in number of referrals to Cerebrospinal Fluid (CSF) shunting procedures and optic nerve sheath fenestration between treatment arms at 0 to 12 months (and at 24 and 60 months). This will be measured on clinical follow-up CRFs.
9. Health economics including cost-effectiveness at 12, 24 and 60 months measured by participant-reported health resource usage questionnaire and EQ-5D-5L and ICECAP-A questionnaires

Sub-study Exploratory Outcome Measures:
1. Change in apnoea-hypopnoea index from 0 to 12 months
2. Change in markers of peripheral neuropathy and metabolic syndrome from 0 to 12 months
3. Change in Magnetic Resonance (MR) imaging (including venous stenoses) from 0 to 12 months
4. Change in cognitive function from 0 to 12 months
5. Change in biomarkers from 0 to 12 (and 24 and 60) months
6. Comparison between IIH patients and the matched control group at baseline with regards to apnoea-hypopnoea index, peripheral neuropathy and metabolic syndrome, MR imaging, cognitive function, and biomarkers
7. Change in MR imaging over a double baseline period of healthy controls

Overall study start date
01/02/2014

Completion date
30/04/2023

Eligibility

Key inclusion criteria
1. Female IIH patients aged between 18 and 55 years, diagnosed according to the modified Dandy criteria who have chronic (> 2 months duration), active disease (visual impairment, papilloedema, significantly raised ICP > 25 cmH2O) and normal brain imaging (magnetic resonance imaging and venography as noted at diagnosis)
2. Body mass index (BMI) >35 kg/m2
3. Tried other appropriate non-surgical treatments to lose weight but have not been able to achieve or maintain adequate, clinically beneficial weight loss for at least 6 months
4. Able to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
90

Total final enrolment
66

Key exclusion criteria
Original exclusion criteria:
1. Age less than 18 or older than 55 years
2. Pregnant
3. Significant co-morbidity, endocrinopathy or the use of hormone-manipulating medication
4. Undergone optic nerve sheath fenestration
5. Definite indication for or contraindication against surgery or dieting
6. Have a specific medical or psychiatric contraindication for surgery, including drug misuse, eating disorder or major depression (suicidal ideation, drug overdose or psychological admission in last 12 months)

Date of first enrolment
06/03/2014

Date of final enrolment
31/10/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals Birmingham
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Study participating centre
Heartlands Hospital
Bordesley Green East
Birmingham
United Kingdom
B9 5SS

Study participating centre
Royal Devon and Exeter Hospital
Barrack Road
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United Kingdom
EX2 5DW

Study participating centre
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Study participating centre
Manchester Royal Eye Hospital
Oxford Road

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M13 9WL

Sponsor information

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Sponsor type
University/education

Website
http://www.birmingham.ac.uk

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research Fellowship, NIHR-CS-011-028

Results and Publications

Publication and dissemination plan

Results will be disseminated through internal reports, relevant conferences, peer-reviewed scientific journals and online publications . First publication date anticipated to be 12 months after the primary outcome measure.

Intention to publish date
31/05/2021

Individual participant data (IPD) sharing plan
The current data sharing plans are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		27/09/2017	22/04/2021	Yes	No
Results article	Sub-study results	22/08/2021	23/08/2021	Yes	No
Results article		05/07/2022	06/07/2022	Yes	No
HRA research summary			28/06/2023	No	No