IIH:WT Trial

IIH:WT is 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 is recruiting at the Queen Elizabeth Hospital, Birmingham. It will also identify potential participants from centres across the country for recruitment and assessment in Birmingham.

The aim of the IIH:WT trial is to assess if weight loss through bariatric surgery and / or dietetic intervention is an effective sustainable treatment for IIH, with sustained reduction of ICP, visual symptoms and headaches.

Open all sections

Design

We will conduct a randomised controlled parallel arm trial where participants will be randomised 1:1 to a bariatric surgery pathway or to a community based Weight Watchers diet programme. Sixty participants (30 to each arm) will be randomised.

The trial will necessarily be open label due to the nature of the intervention though assessors of visual tests, cognitive tests and sleep apnoea tests will be blinded to treatment. The primary outcome, ICP, is not a subjective measure.

Aim of the Study

The aim of the IIH:WT trial is to assess if weight loss through bariatric surgery and / or dietetic intervention is an effective sustainable treatment for IIH, with sustained reduction of ICP, visual symptoms and headaches.

Setting

Suitable patients will be identified at University Hospitals Birmingham (UHB) NHS Trust (as well as from PIC sites across the country). Participants will be randomised at UHB. Participants randomised to the bariatric surgery arm will be referred to the bariatric surgery pathway at Birmingham Heartlands Hospital; participants randomised to the Weight Watchers arm will be enrolled in their local Weight Watchers group.

Target Population

Women with BMI>35kg/m2, with active (papilloedema [Frisen grade ≥ 1] and ICP >25 cmH2O) chronic (over 6 months duration) IIH who have tried other appropriate non-surgical treatments to lose weight but have not been able to maintain weight loss.

Intervention

Participants randomised to the bariatric surgery arm of the trial will be referred to the surgery pathway according to NICE guidelines at Birmingham Heartlands Hospital (BHH), Heart of England NHS Foundation Trust.

Active Control

Participants randomised to the dietetic arm will be given vouchers at baseline, 3, and 6 months that exempt them from paying for consecutive and specified weeks of their local Weight Watchers. They will also be enrolled into their initial meeting. Attendance at the groups will be monitored through participant self-reporting.

Measurement of outcomes & cost

The primary outcome measure is the change in intracranial pressure between baseline and 12 months.

There will be a battery of secondary and exploratory outcome measures that will be used to further investigate the treatment and pathogenesis of IIH. Participants will be followed up for 5 years.