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Eating behaviour in craniopharyngioma

Submission date 04/04/2019	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 10/04/2019	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 09/07/2024	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Craniopharyngioma, although a non-malignant brain tumour, causes major health problems because of its location. It is near vision nerves, the pituitary gland controlling many hormones, and brain centres controlling appetite. Treatment involves surgery and radiotherapy, which can cause further damage. Obesity and associated long-term risks are common, and the reasons are complex. Through this project, we will investigate obesity in young people with craniopharyngioma. We want to find out if obesity is related to overeating from a lack of feeling full, appetite hormones not functioning or low metabolic rate.

Who can participate?
Patients aged between 7-25 years who have a diagnosis of craniopharyngioma

What does the study involve?
First, we will assess whether patients and their families are prepared to take part in research. Second, we will investigate which tests are best to use. We will measure the brain's response to food cues using special MRI scans and appetite hormones levels in the blood, as well as metabolic rate and questionnaires on quality of life and typical eating. Patients will eat lunch, so we can assess food choice and portion size. These measures will be analysed in relation to each patient’s craniopharyngioma severity and treatment, number and type of hormone problems and level of obesity.

What are the possible benefits and risks of participating?
Although craniopharyngiomas are rare (1-2 new childhood patients/per year in the South-west), this project has the potential to identify novel interventions. It will make a real impact to improve quality of life and health in craniopharyngioma patients with unmet complex needs related to obesity. These projects could also help us understand how weight problems could develop after other brain injuries.

Where is the study run from?
University Hospitals Bristol Education & Research Centre, UK

When is the study starting and how long is it expected to run for?
January 2019 to March 2022

Who is funding the study?
UHBristol Research Capability Fund

Who is the main contact?
Dr. Elanor Hinton, elanor.hinton@bristol.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Elanor Hinton

ORCID ID
https://orcid.org/0000-0003-2793-8552

Contact details
NIHR Bristol BRC Nutrition Theme
University Hospitals Bristol Education & Research Centre
Upper Maudlin Street
Bristol
United Kingdom
BS2 8AE
0117 342 1500
elanor.hinton@bristol.ac.uk

Additional identifiers

Protocol serial number
3

Study information

Scientific Title
Evaluating eating behaviours, energy homeostasis and obesity in childhood craniopharyngioma: A feasibility study

Study objectives
The primary research question is whether functional neuroimaging and measurement of appetite hormones are useful tools to investigate hypothalamic obesity and eating behaviour in patients with craniopharyngioma.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 16/11/2018, South West -Frenchay Research Ethics Committee (Health Research Authority, Whitefriars, Level 3 Block B, Lewins Mead, Bristol, BS1 2NT; nrescommittee.southwest-bristol@nhs.net; 0207 1048028), ref: 18/SW/0235, IRAS project ID:250104

Primary study design
Observational

Study design
Observational cross-sectional cohort single-centre feasibility study

Study type(s)
Other

Health condition(s) or problem(s) studied
Craniopharyngioma

Interventions
No intervention in this study.
It is a feasibility study measuring eating behaviour, appetite, functional magnetic resonance imaging (cerebral blood flow, response to food cues and resting brain networks), metabolic rate, OGTT in addition to measuring gastrointestinal hormones.

This study aims to investigate the feasibility of postulated methods of measuring appetite hormones, metabolic rate, neural response to food cues, and to characterise potential disruption between the hypothalamus and cortical limbic system in patients with craniopharyngioma. The insights gained from this feasibility study will inform a future multicentre trial to investigate the safety, efficacy and cost of a novel intervention in patients with craniopharyngioma to address their eating behaviour and obesity.

Objectives
1. Characterise the severity of the tumour, treatment and pituitary dysfunction in the studied craniopharyngioma patient population.
2. Assess whether sufficient patient numbers can be recruited.
3. Assess patient tolerability of the number and nature of measures used in the study.
4. Investigate which measures are the most informative to elucidate the nature of eating behaviour in those with craniopharyngioma-related obesity.

Intervention Type
Other

Primary outcome(s)
1. Characterisation of the severity of the tumour, treatment and pituitary dysfunction in the studied craniopharyngioma patient population. Assessed using a proforma and medical notes once patient recruited into the study.
2. Feasibility outcome (i) can sufficient patient numbers can be recruited (number recruited compared to number on clinic database).
3. Feasibility outcome (ii) patient tolerability of the number and nature of measures used in the study. Measure by an acceptability questionnaire at the end of the study session.
4. Preliminary data on the following: (i) functional MRI (using arterial spin labelling and BOLD fMRI scans), (ii) indirect calorimetry to measure resting metabolic rate, (iii) ad libitum food

consumption (food choice and portion size), (iv) oral glucose tolerance test, measuring glucose, insulin, PYY, ghrelin, GLP-1 (5 time-points before and 30, 60, 90 and 120 post-glucose). (iv) Leptin will also be measured at baseline as well as a full blood count (FBC) and electrolytes (U&Es). (v) Appetite ratings are also given at the same timepoints during the OGTT.

Key secondary outcome(s)
1. Quality of life questionnaire (age appropriate) measured once using the MMQL.
2. Hyperphagic eating behaviour questionnaire
3. Adult or Child eating behaviour questionnaire
4. Body composition measured using multifrequency bioelectrical impedance, Tanita MC-780), to give fat-free mass and fat mass, and total body water

Completion date
31/03/2022

Eligibility

Key inclusion criteria
Patients aged between 7-25 years who have a diagnosis of craniopharyngioma

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
1. Clinically unwell requiring hospital or intensive treatment
2. Unwilling to fast
3. Patients for whom it would be unsafe to have an MRI including those with:
3.1 Certain metal implants
3.2 Tattoos with metallic ink
3.3 Metal body piercings which cannot be removed
4. Pregnancy to avoid harm to the foetus
5. Claustrophobia in the closed MRI environment or unable to tolerate the MRI scanner
6. Weight above 152kg and/or girth greater than 210cm due to size limitations of MRI scanner

Date of first enrolment
25/01/2019

Date of final enrolment
31/03/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Clinical Research and Imaging Centre (CRICBristol)
60 St Michael's Hill
Bristol
United Kingdom
BS2 8DX

Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
UHBristol Research Capability Fund

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository once our analyses have been completed.

The final, anonymised data-set (all measures) will be made available through Pure, the University Research Information System and institutional repository for the University of Bristol. The dataset will become available once the data has been fully analysed by the research team, so hopefully within one year of data collection completion. The research project may also be added

to the Explore Bristol Research (EBR) - the public catalogue of the University's research. This is the weblink to the repository, which will be set up once the data is collected: http://www.bristol.ac.uk/red/research-policy/pure/about/

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		17/05/2023	09/07/2024	Yes	No
Abstract results		15/09/2022	10/03/2023	No	No
Abstract results		17/08/2022	10/03/2023	No	No
Abstract results			10/03/2023	No	No
Abstract results			10/03/2023	No	No
Abstract results	Page 27. P19	12/07/2021	10/03/2023	No	No
HRA research summary			28/06/2023	No	No
Preprint results		11/01/2023	09/03/2023	No	No
Protocol file	version 5	13/02/2020	10/03/2023	No	No