Assessment of changes in symptoms and quality of life after surgical treatment of patients with symptomatic pineal cyst – a prospective observational cohort study

Submission date 17/03/2025	Recruitment status No longer recruiting	Prospectively registered
		☐ Protocol
Registration date 17/03/2025	Overall study status Completed	Statistical analysis plan
		☐ Results
Last Edited 17/03/2025	Condition category Nutritional, Metabolic, Endocrine	Individual participant data
		[X] Record updated in last year

Plain English summary of protocol

Background and study aims:

A pineal cyst is a non-cancerous fluid-filled lump in the pineal gland in the brain. PCs are common and only some are thought to cause symptoms. Until only quite recently, it had been the understanding of the medical community that PCs don't cause symptoms. However, several studies published since 2015 have shown that the majority of patients with symptoms (headaches; visual disturbances; balance and hearing problems; memory, speech and other cognitive impairment etc) improve following surgical removal of the cyst. These are early studies, based on a review of clinical records of a relatively small number of patients. As helpful as these studies are, a higher level of clinical evidence is required to reduce the uncertainty about the role of surgery in the management of symptoms of patients with symptomatic pineal cysts (SPCs). The aim of this study is to collect comprehensive and beforehand agreed information about the symptoms and quality of life of patients with SPCs before and after surgery to remove the PC. Comparing the information about symptoms and quality of life from before and after surgery will not only help our understanding of the value of surgery in SPCs but will also help calculate the probability of each symptom improving following surgery.

Who can participate?

Patients aged over 18 years with SPCs

What does the study involve?

Participants will be asked to fill in a questionnaire before the operation, asking about their overall quality of life as well as about specific symptoms. Three months and 12 months after surgery, patients will be asked to fill in a new questionnaire to monitor their progress.

What are the possible benefits and risks of participating?

There will be no direct benefit to patients as a result of participation in the study. However, it is hoped that the detailed information about symptoms and quality of life will help us better understand your symptoms and related quality of life as well as patients with symptomatic

pineal cysts in general.

There are no real disadvantages in taking part in the study as it does not influence the course of treatment.

Where is the study run from? The Cambridge University Hospital (UK)

When is the study starting and how long is it expected to run for? July 2021 to May 2024

Who is funding the study?

The study is organised by a research group from the Departments of Neurosurgery, National Institute for Health Research and the Cambridge Clinical Trials Unit. The study is run by highly experienced medical scientists who do all the work related to this study on a voluntary (unpaid) basis.

Who is the main contact?
Mr Thomas Santarius, maria.harrington@addenbrookes.nhs.uk

Study website

https://cam-pc.org/

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

292313

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

IRAS292313

Study information

Scientific Title

Cambridge prospective cohort study of surgical treatment of patients with symptomatic pineal cyst

Acronym

CamProS-PC

Study objectives

The shortage of high-quality evidence to inform the management of patients with pineal cysts with symptoms in the absence of ventriculomegaly (nhSPC) underlies the lack of consensus on the management of this condition. We are working towards conducting a large-scale randomised controlled trial (RCT) to assess the safety and efficacy of pineal cyst resection in the management of the nhSPC syndrome. This prospective cohort study aims to prospectively collect patient-reported outcomes from 40 patients who underwent cyst resection as treatment of nhSPC, in order to assess the feasibility of conducting a definitive RCT.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 09/07/2021, HRA and Health and Care Research Wales (HCRW) (HRA, 2 Redman Place, Stratford Cross, London, E20 1JQ, United Kingdom; +44 (0)20 7104 8000; contact@hra.nhs.uk), ref: 21/NI/0120

Study design

Single-centre observational cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Quality of life, Safety, Efficacy

Participant information sheet

https://cam-pc.org/

Health condition(s) or problem(s) studied

Pineal cyst with symptoms without hydrocephalus

Interventions

Pineal cyst resection

Participants will be asked to fill in a questionnaire before the operation, asking about their overall quality of life as well as about specific symptoms. Three months and 12 months after surgery, patients will be asked to fill in a new questionnaire to monitor their progress.

Intervention Type

Procedure/Surgery

Primary outcome measure

Quality of life improvement by 20 points in the Role Functioning scale score of the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire – C30 (EORTC QLQ-C30) at 12 months postoperatively as compared to preoperatively

Secondary outcome measures

- 1. The effect of surgery on all other domains of the EORTC-QLQ-C30 questionnaire at 3 months, 12 months and every subsequent year postoperatively compared to the preoperative level: Global quality of life (QL2), Physical functioning (PF2), Emotional functioning (EF), Cognitive functioning (CF), Social functioning (SF), Fatigue (FA), Nausea and Vomiting (NV), Pain (PA), Dyspnoea (DY), Insomnia (SL), Appetite loss (AP), Constipation (CO), Diarrhoea (DI), Financial difficulties (FI).
- 2. The rate of symptom improvement at 3 months, 12 months, and every subsequent year. Specifically, the symptoms assessed are the following: overall, headache, dizziness/balance, hearing/tinnitus, vision, memory, concentration, and sleep. The assessment scale consisted of six levels: much worse, worse, no change, better, much better, I no longer have this symptom.

 3. The safety of the intervention assessed by prospectively collecting complications immediately after the operation, at 3 months, 12 months and every subsequent year postoperatively.

Overall study start date

01/07/2021

Completion date

31/05/2024

Eligibility

Key inclusion criteria

- 1. Age >18 years
- 2. Presence of a pineal cyst (PC) of size >10 mm
- 3. Presence of severe symptoms consistent with the syndrome of nhSPC, defined as $\geq 6/10$ on an established severity scale
- 4. Minimum of 6 months of conservative treatment without improvement

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

40

Total final enrolment

40

Key exclusion criteria

- 1. Radiological evidence of ventriculomegaly
- 2. Other diagnosis of CNS pathology, including neoplasm, vascular (ischemic or haemorrhagic), traumatic, or hydrocephalus
- 3. History of intracranial neurosurgical intervention

Date of first enrolment

01/01/2019

Date of final enrolment

31/05/2023

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Cambridge University Hospitals NHS Foundation Trust

Cambridge Biomedical Campus Hills Road Cambridge United Kingdom CB2 0QQ

Sponsor information

Organisation

Cambridge University Hospitals NHS Foundation Trust

Sponsor details

Hills Road Cambridge England United Kingdom CB2 0QQ +44 (0)1223 805000 cuh.research@nhs.net

Sponsor type

Hospital/treatment centre

Website

http://www.cuh.org.uk

ROR

https://ror.org/04v54gj93

Organisation

University of Cambridge

Sponsor details

The Old Schools
Trinity lane
Cambridge
England
United Kingdom
CB2 1TN
+44 (0)1223 337733
croenquiries@admin.cam.ac.uk

Sponsor type

University/education

Website

http://www.cam.ac.uk

ROR

https://ror.org/013meh722

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in peer-reviewed journal

Intention to publish date

01/05/2025

Individual participant data (IPD) sharing plan

The datasets generated in the current study will be published as a supplement to the results publication

IPD sharing plan summary

Published as a supplement to the results publication