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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

Registration date
17/03/2025

Overall study status
Completed

Last Edited
17/03/2025

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] 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 ≥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
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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