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INFORMATION SHEET:
PATIENTS

Version number: 1.2
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Title of Project: **Assessment of changes in symptoms and quality of life after surgical treatment of patients with symptomatic pineal cyst - a prospective observational cohort study**

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish.

Thank you for reading this.

***Part 1** tells you the purpose of this study and what will happen to you if you take part.*
***Part 2** gives you more detailed information about the conduct of the study.*

Please ask if anything is not clear or if you would like more information. Take time to decide whether or not to take part.

Part 1

What is the purpose of this study?
Following our discussion in the clinic you will know that pineal cysts (PCs) are common and that only some PCs 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 review of clinical records of 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 our study is to collect comprehensive and beforehand agreed information about symptoms and quality of life of patients with SPCs. Some patients will choose to undergo surgery while others will choose to be treated by non-surgical means. 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 calculating the probability of each symptom improving following surgery. Questionnaires from patients who choose not to undergo surgery will help improve our understanding of symptoms of patients with SPCs over time and also see whether there is a difference in the type and severity symptoms between patients who choose to undergo surgery and those who prefer non-surgical management.

Why have I been invited to participate in the study?
We are inviting all adult patients with the diagnosis of symptomatic pineal cysts (SPCs).

Do I have to take part?
It is up to you to decide. We will describe the study and go through this Information Sheet, which we will then give to you. If you feel you would like to participate in this study, we will then ask you to sign a consent form to show that you have agreed to take part. You are free to withdraw your consent at any time, without giving a reason. Not taking part in of withdrawing from the study will not affect in any way they type of treatment or the standard of care you will receive.

What will happen to me if I take part?
Your preparation for surgery, surgery and aftercare will essentially be the same as if you did not participate in the study. The only activity that relates to the study are Quality of Life and Symptom questionnaires that we will ask you to fill in before surgery (or at diagnosis, if you chose not to undergo surgery) and at 3, 12, 24 and 36 months following surgery (following diagnosis, if you chose not to undergo surgery). These questionnaires will also help us with following your progress in more detail.

Will taking part interfere with my treatment?
Taking part will have no effect on the treatment you will receive. Likewise if you decide not to proceed with this study or leave the study at any point, it will not alter the treatment that you will receive.

What are the possible disadvantages and risks of taking part?
There are no real disadvantages in taking part in the study as it doesn not influence the course of your treatment.

Will my GP be informed?
We won't routinely inform your GP unless you specifically ask us to. We believe that there is no benefit in routinely informing GPs because participation in the study will have no immediate or long-term effects on your health.

What are the possible benefits of taking part?
There will be no direct benefit to patients as a result of participation in the study. However, we hope the detailed information about your 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.

What if there is a problem?
Any complaint about the way you have been dealt with during the study or any suggestion of possible harm will be investigated and addressed as required. The detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?
Yes. We will not inform anyone of your participation in the study without your consent. All information gathered about you during the study will be kept confidential. The details are included in Part 2.

Contacts for further information.

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For further independent assistance, please contact:

Patient **A**dvice & **L**iaison **S**ervice (PALS)
Box 53,
Cambridge University Hospitals NHS Foundation Trust,
Hills Road,
Cambridge CB2 0QQ

Tel: 01223 216 756
From bedside Patientline: *801

E-mail: pals@addenbrookes.nhs.uk

This completes part 1 of the Information sheet.

Part 2

What if relevant new information becomes available?
Sometimes we get new information about the problem being studied. If this happens, your research doctor will tell you and discuss whether you should continue in the study. If you decide not to carry on, your research doctor will make arrangements for your care to continue. If you decide to continue in the study they may ask you to sign an updated consent form. If the study is stopped for any other reason, we will tell you. This will not affect your care in any way.
This is, however, an extremely unlikely consideration in this study.

What will happen if I don't want to carry on with the study?
You can withdraw from the study at any time without giving a reason. Information that was already collected may still be used, unless you will ask not to use it. Your withdrawal will not affect your care in any way.

What if I am unhappy with things or something goes wrong?
If you have concerns about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (please see contact details at the end of Part 1). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the Addenbrooke's Patient Advice and Liaison Service (PALS).

Are there compensation arrangements if something goes wrong?
In the unlikely event of anything untoward happening as a result of you taking part in the study, all patients registered with Cambridge University Hospitals NHS Foundation Trust are covered by the Trust's indemnity. In addition, clinical staff carry their own personal insurance. In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Cambridge University Hospitals NHS Foundation Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Who is organising and funding the research?
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 voluntary (unpaid) basis.

Who has looked at and approved the study?
All research in the NHS is looked at by an independent group of people called the Research Ethics Committee. The Committee is setup to review each project carefully to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by the Research Ethics Committee.

Confidentiality – who will have access to the data?
All information which is collected about you during the course of the research will be kept strictly confidential and any clinical data will be fully anonymised before being used for research. At present we have no plans to share any of these anonymised data with data with researchers at other institutions. However, we may potentially do this in future if we were to set up a larger, multi-institutional study to better understand your condition and its treatment. If we were to do this, i.e. contribute your fully anonymised data to national or international studies, we would first seek approval of the Ethics Committee.

MRI scans that are taken as part of your routine clinical care are saved with personal identifiable information such as your name. However, this will be used for research purposes only after being anonymised and will be unidentifiable.

Data collected during the study will be stored on a secure network belonging to the Cambridge University Hospitals (CUH). All data will by anonymised and only members of the research group at the Departments of Radiology and Neurosurgery will have access to the data. Cambridge University Hospitals (CUH) is deemed to be the Data Controller and all enquiries concerning access to the data should be addressed to it. The Administrator of the Centre will be able to tell you the name and address of the relevant officer.

What will happen to the study results?
The data will be kept securely for a minimum of 10 years and possibly indefinitely in the Departments of Neurosurgery in accordance with good research practice. It is our aim to share the results of the study with other scientists and health care professionals. The results will therefore be published in peer-reviewed scientific journals, internal reports, conference presentation, publication on websites and other forms of scientific dissemination. All disseminated results will be anonymised and unidentifiable.

Will video/audio tapes be used?
No.

You may withdraw from the study at any time without explaining why and it will not affect the present or future treatment in any way.

GCPR statement
Cambridge University Hospitals NHS Foundation Trust (CUHNFT) is the Sponsor for this study based in the United Kingdom. They will be using information from [you and/or your medical records] in order to undertake this study and will act as the data controller. This means that this organisation is responsible for looking after your information and using it properly. CUHNFT will keep identifiable information about you for x years after the study has finished/ until x].Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information using the following links:

For Cambridge University Hospitals NHS Foundation Trust, please visit: https://www.cuh.nhs.uk/corporate-information/about-us/our-responsibilities/looking-after-your-information, or email the Data Protection Officer at: gdpr.enquiries@addenbrookes.nhs.uk

This research study has been approved by the Research Ethics Committee.

Contacts for further information

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From bedside Patientline: *801

E-mail: pals@addenbrookes.nhs.uk

Thank you for considering taking part in this study. Our research depends entirely on the goodwill of potential volunteers such as you. If you require any further information, we will be pleased to help you in any way we can.