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MAIN STUDY PATIENT INFORMATION SHEET
Version 5.0

The **N**asal **Air**way **O**bstruction **S**tudy
NAIROS

Please read this information sheet before coming to clinic to discuss treatment options for your blocked nose.

Invitation

We are inviting you to take part in a research study. Please read the following information to help you decide if you want to take part. It will explain why we are doing this research and what it might mean for you. You don't have to decide straight away and you can talk to your friends/family about it. If you have any questions or if you want to know more, please don't hesitate to contact your local hospital staff on the numbers listed at the end of the information sheet.

Key Points

- You might find it helpful to watch our video for patients : http://www.nairos.co.uk/
- Doctors do not know whether surgery (septoplasty) or medical management is the best method for treating problems with a blocked nose (nasal airway obstruction).
- NAIROS aims to find out which treatment works better and which treatment should be used widely in the NHS.
- Patients who agree to take part are randomly allocated to either medical management or surgery.
- Medical management involves using a nasal steroid spray and a salt-water spray in each of your nostrils twice daily for 6 weeks then once or twice daily for the remainder of the 6 months, to shrink the swelling of the nasal lining to improve nasal airflow.
- Surgery (septoplasty) is an operation under general anaesthetic to straighten the septum to improve nasal airflow. The septum is the part of the nose between the two nostrils.
- We need to see you 3 times throughout the study; the first visit (this is when you decide if you would like to take part), at 6 months and at 12 months.
- Information will be collected on health, quality of life, concerns, and costs to patients. We will also measure how much air flows through each nostril at each visit.
- All patients who take part in NAIROS will be given the option to have

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Please read the following information to see if you may be interested in taking part.

Why is NAIROS needed?

We do not know what the best treatment is for people with a blocked nose (nasal airway obstruction).

Why have I been invited to take part in NAIROS?

You have been referred to the Ear Nose and Throat clinic as you have had problems breathing through your nose ("nasal airway obstruction").

The nasal airway obstruction could be due to inflammation and mucus, which can make breathing difficult through the nose. A twisted septum can cause problems with breathing through the nose, but it is not always the cause of nasal airway obstruction. Sometimes people with a very twisted septum can still breathe fine through their nose. Some people who have a septoplasty find they still have problems with a blocked nose after their operation. At the moment doctors don't know whether the best thing to do is straighten the twisted septum with an operation or to use medicines to help unblock the nasal airways.

Do I have to take part?

No, it is up to you to decide if you want to take part in NAIROS. If you do not want to take part, you will get a treatment plan agreed with your doctor. If you agree to take part, you can change your mind and withdraw from the study at any time without having to give a reason. If you decide not to take part, your study doctor would like to record your reasons why.

What does taking part involve?

If you decide to take part, you will join one of two NAIROS groups. Group 1 will receive medical management, and Group 2 will receive surgery.

Group 1: Medical Management

If you are put in group 1, you will be given mometasone (steroid) spray and a salt water spray to use for the next 6 months. The salt water spray should be taken before the mometasone spray. We will then see you in clinic at 6 months and at 12 months to complete questionnaires, measure your nasal air flow, carry out a clinical examination and see how you are doing.

Group 2: Surgery

If you are put in group 2, you will undergo a surgical operation. Your surgery should take place within 8 weeks. We will then see you in clinic at 6 months and at 12 months to complete questionnaires, measure your nasal air flow, carry out a clinical examination and see how you are doing.

The group you are allocated to will be determined by chance, through a process called 'randomisation'. This process will help us to achieve two groups of patients that are similar in every respect, with exception of the treatment they receive. This will help us to fairly compare these treatments at the end of the study. Neither you nor your doctor can choose the group you are assigned to. To take part, you must be prepared to have either medical or surgical management. If you are allocated to surgery, you must be prepared to have surgery within 8 weeks.

What will happen first?

Your GP may have referred you to an Ear Nose and Throat clinic with a nasal airway obstruction or a suspected twisted septum (midline nasal partition). A member of the Ear Nose and Throat team will have sent you an appointment for the Ear Nose and Throat clinic.

When you come for your appointment, a member of the NAIROS team will ask if you have read this information sheet. If you have read it and would like to take part you will be asked to sign a consent form so we can assess whether you are suitable to take part in the study. If you don't want to take part, that is absolutely fine: your appointment will go ahead exactly as planned, and your treatment and care, will not be affected in any way by your decision. To check whether you are suitable for this study, we need to conduct a routine examination of your nose and ask a few questions about your condition using 2 short questionnaires. With your permission we would like to keep these results for research purposes.

We will ask your permission to audio-record the initial consultation about NAIROS when your treatment options are discussed, until you have decided whether or not to take part in the study. This audio-recording will help us to improve the way we explain the study to patients. If you agree to have your appointment audio-recorded, you will be asked to sign a consent form. We are audio-recording appointments because we know little about how people make decisions about whether or not to take part in clinical research. One way to improve our knowledge is to audio-record conversations you have with hospital staff about possible participation in NAIROS. This will help us understand how information is presented to you and to improve the way we talk to patients about research in the future. You can also take part in NAIROS, even if you don't want to take part in the audio-recording and interview study.

When you come to the clinic, you will be shown a DVD, which discusses the study further. You will also have the opportunity to discuss the study with health care professionals to help you decide whether or not you would like to take part. If you decide to join the main NAIROS study, you will be asked to sign a consent form.

What will I have to do if I take part?
The NAIROS team will need to see you again at 6 months and at 12 months after you have agreed to take part in the study.

- At each visit you will be asked to complete 4 short questionnaires (which should take no longer than 30 minutes to complete). We will also measure your nasal airflow and perform a clinical examination of the inside of your nose. Please note the machine we use to measure your nasal airflow (NV1 Rhinospirometer) may not function properly near electromagnetic devices, so please make sure your mobile phone and other electronic devices are switched off.

- We will ask you for permission to use some information that has already been collected about your nasal blockage and its treatment as part of your standard clinical care.

What is medical management?

- You will be given a 6 month supply of salt water nasal spray and a steroid nasal spray (mometasone) to use in each nostril. It is important to use this as prescribed. The combination of the salt water spray and the steroid spray may improve nasal airflow by reducing the swelling in the nose, which may be making your nose feel blocked.

What is it like to have surgery on the nose septum?

The operation is performed whilst you are asleep (under a general anaesthetic). The operation takes about 30-45 minutes. The surgery involves making a small cut to the lining inside your nose. We then straighten out the septum by taking away some of the cartilage and bone, moving the rest of the septum back to the middle of the nose. Then we hold it all in place with some stitches. The surgery is usually done as a day case, i.e. no overnight stay. For further information on the surgery please see the following weblink: www.entuk.org (click on patient information; select 'About septal surgery').

After surgery you;

a. may have a little bleeding from the nostrils in the first few days.
b. will be asked to wash out your nose twice daily with salt water (saline douche) plus use Naseptin cream (or Bactroban if you are allergic to peanuts)
c. are likely to require some time off work to recover.

What happens after 6 months?

Regardless of the group that you have been allocated to, your NAIROS doctor will review your treatment at 6 months. You will have a chance to discuss medical or surgical treatment if your symptoms haven't improved. If you are on medical management and want to continue with a nasal spray, you may have to pay for this on prescription. If you have had surgery and still have symptoms, you may choose to try a nasal spray, but you may have to pay for this on prescription.

What happens if I decide I don't want to continue with the treatment I am allocated to?

You are free to discontinue the study treatment at any time. If you stop treatment, we would request that you continue to fill out questionnaires and attend follow-up visits. Please discuss this with a member of your local study team.

Patient Telephone Interviews

During the study, we may contact you to ask if you would like to take part in a telephone interview with a researcher from Newcastle University or the University of Bristol. This would be about your views and experiences of the NAIROS study. We would like to interview patients who have joined the main NAIROS study, as well as patients who have decided not to take part in the main NAIROS study. We will seek your permission to contact you about this on the informed consent form. This is separate from the main NAIROS study. You do not have to take part. You will have the option to find out more or decline if you wish. Please note not all participants will be contacted.

- The telephone interview will take around 40 minutes. If you agree your interview with the researcher will be audio-recorded.

- If you decide not to take part in NAIROS, we would like to ask your permission to contact you once – about 1 to 2 weeks after we spoke to you about NAIROS. This interview will explore your views on the information you received about the NAIROS study.

- If you consent to NAIROS, we may contact you twice – once at the start (to understand your views about taking part) and again after 6 months or at 12 months to find out how you got on with either the surgery or the medical management. Further details about the interview and audio-recording study are provided at the end of this information sheet.

Expenses and Payments
We will pay your travel expenses to get to the hospital for two study visits at 6 months and at 12 months. This will be up to a maximum of £25 per visit.

What happens when NAIROS stops?
At the end of NAIROS you will continue to receive usual clinical care as decided by your hospital and doctor. We hope that the results of NAIROS will help us say which treatment should be widely used in the future.

What are the benefits of taking part?
There may be no direct benefits to you for taking part in this study. NAIROS aims to help future patients and their doctors make better decisions about nose blockage treatments. All NAIROS patients will undergo very careful monitoring of their nasal problems before and after treatment, whether that be medical management or surgery.

What are the disadvantages or risks of taking part?
All of the treatments in the NAIROS study are already used to treat patients in the NHS, so the risks are no more than with usual care. Please see the risks for surgery and medical management below.

In addition to risks associated with surgery or medical management, extra time is required to fill in forms and for the extra visits to hospital – but we will pay a contribution to your travel expenses for these (as described above).

Risks of Having Surgery
Minor risks include:
- A sore throat which will usually settle in a day or two with paracetamol treatment
- Discomfort in the nose, congestion and minor ooze of blood from nose
- Ongoing symptoms of blocked nose

Rare risks include:
- Scarring inside the nose
- Decreased sense of smell
- Perforation (hole in the septum which can cause whistling noise while breathing through your nose)
- Minor change in nose shape
- A repeat operation.

Please note septoplasty is routinely carried out in your hospital. All of the staff have been fully trained.

Risks of Medical Management

Minor risks include:

- Bleeding or nasal crusting
- Dryness or irritation of nose and throat
- Ongoing symptoms of blocked nose

Pregnancy

- **If you become pregnant during the study**
- **If you think you may be pregnant**
- **For male participants in the medical management arm only – if your female partner becomes pregnant**

If any of the above apply to you, it is important that you tell your doctor straight away (see contact details on page 6 of this information sheet).

Pregnancy

To take part in the study, women must not be pregnant or be breast feeding for the 12 month duration of the study.

What are the possible risks or disadvantages of taking part in the audio-recording and interview study?

There are no physical risks to taking part. It is possible that talking about issues related to health and clinical care can cause some people anxiety. If this happens, the interview can be paused or stopped at any time, and there will be no obligation to continue.

What are the possible benefits of taking part in the audio-recording and interview study?

We cannot promise the study will help you directly, but the information we get will help us to improve how we communicate information about NAIROS and similar clinical studies in the future.

Will my taking part in the audio-recording and interview study be kept confidential?

All information collected about you during the course of the study will be kept strictly confidential. Information about you held at the coordinating sites at the University of Bristol and Newcastle University will be stored on an online secure database and will only be accessed by authorised members of staff involved in the research. Audio-recorded data will be securely transferred to the University of Bristol to be used for research and training**.** All audio-recordings (from consultation appointments and interviews) will be labelled with a reference number (not with your name) to hide your identity. Recordings will be transcribed (i.e. a written record of the interviews produced) by the researchers or a University of Bristol or Newcastle employee or by a University of Bristol or Newcastle approved contracted transcribing service. These transcripts will also be anonymised so that you cannot be recognised from any of the information we collect from you.

Further supporting information:

Can I help with research if I do not want to participate in NAIROS?

If you are eligible for the NAIROS study but do not want to participate, you do not have to give any reason and your care will not be affected in any way.

You will be offered an opportunity to provide anonymous data, which would help us to compare participants with all patients who have been referred. This comparison data will ask you for your gender, age, nasoendoscopic results and to complete 2 short questionnaires, NOSE symptoms assessment questionnaire and the Sino-Nasal outcome test (SNOT22) questionnaire. You can also choose to take part in the interview study without doing the main NAIROS study.

What will happen if I don't want to carry on in the study?

You can withdraw your consent at any time and for any reason, without having to tell us your reason. You will be fully cared for and supported as per your hospital's standard practice. We will keep any information that we have already collected about you in the study.

What if there is a problem?

If you are not happy with any part of NAIROS, you should speak first to the study team, who will do their best to help you. **Their contact details are on page 9.** If you are still unhappy you may wish to raise your concerns with someone who is not directly involved in your care. You can contact the Patient Advice Liaison Service (PALS) who provide a confidential service on 0800 0320202 or <site to localise with Local phone number and email address>

In the unlikely event that you are harmed during the research and this is due to someone's negligence (they were careless) you may have grounds for legal action for compensation, but you may need to meet your own legal costs. NHS indemnity does not offer no-fault compensation (for harm that is not anyone's fault).

Will my GP be told about my involvement in NAIROS?

Yes, we will inform your GP that you are taking part in NAIROS. It will also be noted in your hospital medical records so that staff in the hospital know you took part in the study.

What will happen to the results of the study?

- The study is due to finish at the end of 2020.
- The results will be written in medical journals and presented in meetings to other doctors, nurses and researchers. The results might be shared with other researchers and to help with future studies.
- A report will be written for the study funder – the National Institute for Health Research – and put on their website.
- The overall results will also be available at the end of the study on our website http://www.nairos.co.uk/ .

Will the information about me be kept confidential?

Yes. All of the information collected will be entered on computers that are kept secure and password protected.

- We will use a unique study number to identify you instead of using your name.
- Recordings of your voice will be kept secure and any transcripts (written out version) will be anonymised (not include your name or anything that could identify you).

- The local study team at <insert NHS site name> and the researchers at the University of Bristol and Newcastle University will keep a note of your contact details and email address for any telephone interviews or follow up questionnaires you agree to take part in. They will be stored with password protection and only used for this reason.
- Your contact details and email address will never be shared with anyone else.
- You will not be named in any results, reports or anything on our website.

What will happen to my data?

The study information about you and your hospital notes will be looked at by people directly involved in the study, as well as by people who are checking the study is running as it should. This may include staff from the Newcastle Clinical Trials Unit at Newcastle University, and the University of Bristol as they are managing the study. It may also include regulatory authorities, sponsor and funder.

Audio-recordings of any conversations you give us permission to record will be kept securely for 10 years after the end of the study in case we want to check the transcripts, and then they will be deleted.

We will ask your permission to share data from the study which has been made anonymous (does not contain any identifying information) with other researchers not related to this study. This data would be stored indefinitely in an online database, which can be accessed by approved individuals who are interested in conducting their own analyses of the data. These individuals will have to submit an application to do this, which will be assessed by an independent committee. Sharing research data and findings is considered good research practice and is a requirement of many funding bodies and scientific journals. Sharing data helps to maximise the impact of money invested into conducting research studies, and can encourage new avenues of research.

All other identifiable participant research data will be stored for up to 5 years.

Who is organising and funding NAIROS?

The main study doctor (also called the 'Chief Investigator') is Mr Sean Carrie, a Consultant Ear Nose and Throat Surgeon at Newcastle Upon Tyne Hospitals NHS Foundation Trust. The study team also includes senior doctors and nurses, and university experts in research studies.

It is managed by the Newcastle University Clinical Trials Unit on behalf of the study sponsor - The Newcastle upon Tyne Hospitals NHS Foundation Trust. It is funded by the NHS National Institute for Health Research, Health Technology Assessment Programme.

Up to 17 hospitals will be taking part in the NAIROS study. Each hospital has a study doctor, called an 'Investigator'. The Investigator in your hospital is …… A full list of centres and Investigators is available on our website. http://www.nairos.co.uk/

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. NAIROS has been reviewed and given a favourable opinion by Newcastle and North Tyneside2, Research Committee.

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Patients have been involved in deciding how to do NAIROS from the start. For example, patients were supportive of the DVD we have prepared which tells you about the study.

What if I have any questions?
Please ask the doctor or nurse who is looking after you. They can put you in touch with the research team or the Investigator for NAIROS at your hospital.

What happens next?
You can take time to think about the study and whether you want to take part. A member of the research team will speak to you when you come in for your initial visit. They will go through this information sheet with you and answer any questions before you make your final decision.

You can find more information and the progress of the study on our website:
http://www.nairos.co.uk/

NAIROS team contact details for your hospital:

Principal Investigator:
Address:

Tel:

Research Nurse:
Address:

Tel:

This study was funded by the NIHR HTA Programme (ref 14/226/07).

Thank you for taking the time to read this information sheet.

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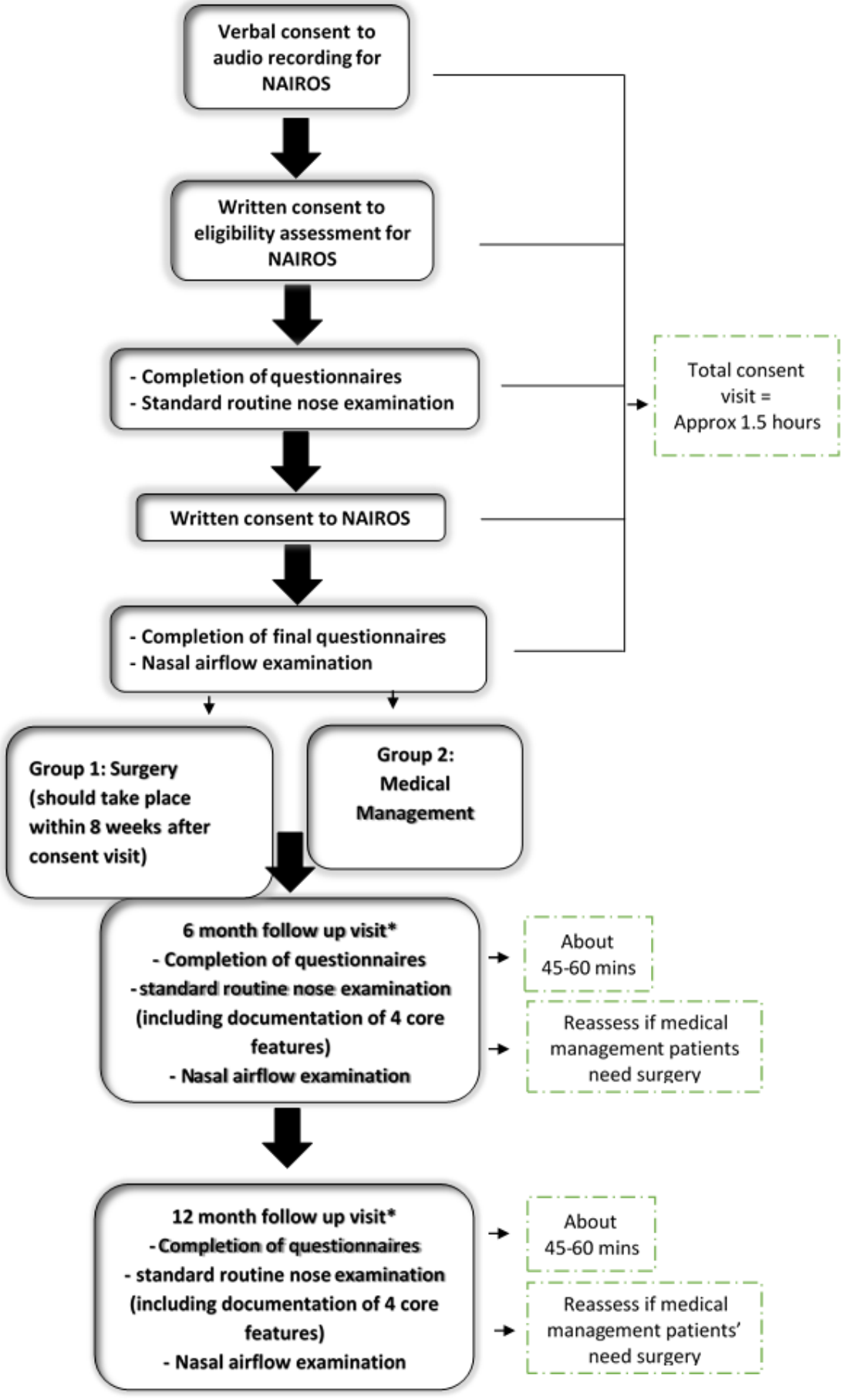
This diagram shows you what happens during NAIROS and how long it will take:



*Questionnaires for the 6 months and 12 months visits can be completed in person or sent by post