(To be printed on Trust headed paper)

NATTINA

The **NA**tional **T**rial of **T**onsillectomy **IN A**dults: a clinical and cost effectiveness study

Participant Information Sheet

PART 1

We would like to invite you to take part in a research study called NATTINA. Before you decide you need to understand why the research is being done and what taking part would mean for you. Please take time to read the following information carefully before you decide, and feel free to talk to others about the study, if you wish.
NATTINA is a national study, in which the NHS research department has invested over £1.75 million in order to achieve better treatment plans for adults like yourself with sore throat. Patients are being recruited in 28 hospitals in England, Scotland and Wales. Thank you for your interest in 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 us if there is anything that is not clear.

What is the purpose of the study?

Sore throats cause many adult hospital admissions in the UK each year but doctors do not know the best approach to treating severe sore throat. Removal of the tonsils (tonsillectomy) may be done for severe sore throats but we need more information about how to treat sore throats best.

We need to understand more about:

- Which patients will benefit most from surgery?
- The types of sore throats people might continue to have after the operation?
- Which patients will best be treated with antibiotics and or pain killers

In the NATTINA study we want to investigate the effectiveness and costs of tonsillectomy compared with painkillers/antibiotics (conservative management) in adults with frequent sore throats. Therefore, participants will be randomly assigned to either receive a tonsillectomy or conservative treatment (with deferred surgery). **Please note if you decide you are not happy with the treatment (tonsillectomy or conservative treatment) in the study, you have the**

option to call the research team and switch to the other treatment. We plan to compare the number of sore throat days that may be experienced after each approach which may help us make better NHS guidance about who can benefit most from surgery.

Please take an opportunity to look at the NATTINA website for more information - www.NATTINA.com and watch the information DVD.

Why have I been invited to take part in NATTINA?

You have been invited to take part in NATTINA because your GP has referred you to an Ear, Nose and Throat (ENT) specialist to discuss treatment options for managing recurrent acute tonsillitis.
You will not be able to take part in the study if you:

- Are not willing to undergo a tonsillectomy or receive the conservative therapy option
- Are attending as an emergency admission
- Are pregnant or breast feeding
- Suffer from primary sleep breathing disorder
- Suffer from bleeding diathesis (tendency to bleed)

Do I have to take part?

You do not have to take part. Your participation in this study is voluntary and it is up to you to decide. You can withdraw from the study at any time, without giving a reason, and this will not affect the care that you receive.

What will happen to me if I take part?

If you wish to take part in the study and have been sent this Participant Information Sheet in the post before your outpatient referral visit, you will have the opportunity to discuss the study with the clinician or research nurse at the referral visit and ask any questions. You will be asked to give written consent on an Informed Consent Form before any trial procedures can take place. If you first received information about the study at your referral visit you will be invited to attend an appointment at a later date where you will have the opportunity to consent to the study. If you would like more time to consider, ask your clinician or research nurse to arrange a future appointment. Your consent form will be faxed to the Newcastle Clinical Trials Unit who are managing the study.
After consenting, you will then be randomised and allocated one of the following 2 groups:

- Immediate tonsillectomy – you will receive a tonsillectomy within 6-8 weeks

Or

- Conservative management (surgery deferred up to 24 months) – you will follow the usual care pathway which allows the use of any over-the-counter pain killers you wish to take on a need to use basis, attendances to the GP for antibiotics or walk in clinics/A&E for more serious episodes.

Your clinician will inform you on the same day about which group you have been allocated to.

What will I have to do?

Regardless of which group you are randomised to, you will be asked to complete a questionnaire package at the baseline visit and will be followed up for 24 months after randomisation.

Your participation involves the following:

1. Each week of the study we shall ask you how many sore throat days you have had that week by your preferred choice of contact - text message, email or a voice response via telephone. Please note texts and emails are sent out automatically and the phone number or email address cannot be used to contact the clinical team. Your responses will be anonymous and will not be shared with the trial clinicians. If you need to contact the clinical team at the hospital because of your sore throat or surgery, please see the contact numbers in part 2.

2. If you experience a sore throat during the study, we will ask you to submit a NATTINA Sore Throat Alert Return – or STAR for short. The STAR includes:
    - Whether your sore throat is severe or mild to moderate
    - If you have had to use any over-the-counter or prescription medicines
    - If you have been seen by your GP or other healthcare service, or sought any professional advice (e.g. pharmacist)
    - The number of days when unable to undertake usual activities or took time off work
    - A short 12-item general health questionnaire

3. If you are in the tonsillectomy group the Research nurse will call you at home at one and two weeks after your surgery to see how you are doing and if you have had any side effects related to the operation.

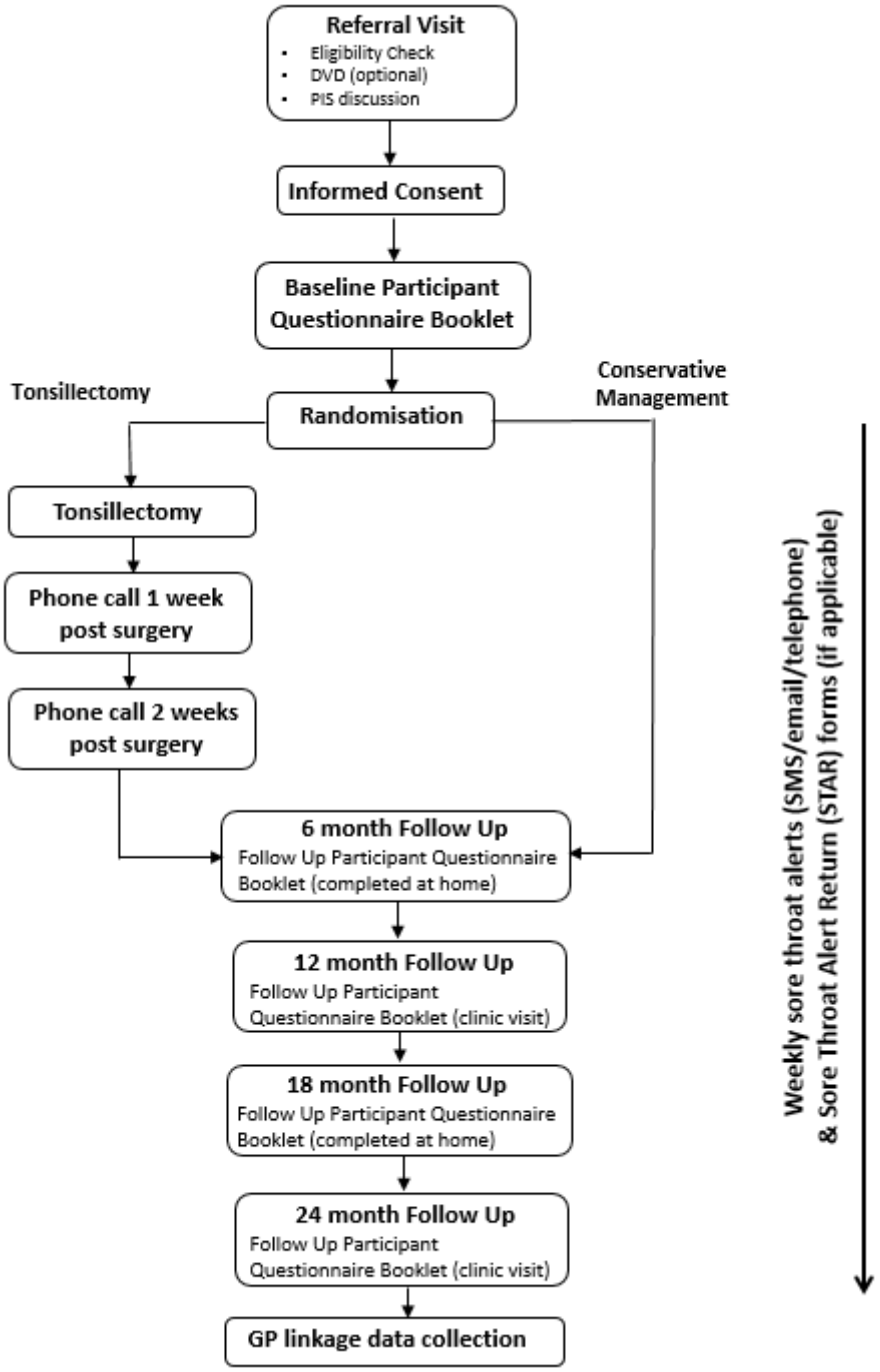
4. We will review you in the outpatient clinic at 12 months. If you are in the deferred surgery group, we will ask if you are happy to remain in that group for a further 12 months. All participants will be asked to complete a short questionnaire package at this visit.

5. We will ask you to complete a short questionnaire package at home at 6 and 18 months after randomisation.

6. At the end of the study – 24 months from the start, you will be given a final questionnaire package. If you are in the deferred surgery group and your sore throats meet the NHS guidelines for a tonsillectomy, you will be offered the chance to have tonsil surgery.

7. During the study we may contact you to ask if you would like to take part in an interview with a researcher from Newcastle University to discuss your expectations, experiences and views on the study and sore throats. We will seek your permission to contact you about this on the informed consent form. The interviews are not compulsory and you will have the option to find out more or decline if you wish. Not all participants will be contacted and interviews will be arranged at a time and location convenient for you.

The flowchart on the following page explains this process.



Expenses and payments

To say thank you for completing the questionnaires and weekly returns in the study, we are happy to be able to offer you a £25 high street gift voucher at the end of your 1st and 2nd year

follow up visits. We will also contribute towards your travel expenses for the 2 clinic visits at 12 months and 24 months. As a further gesture of thanks to those who take part in an interview you will receive an additional £15 high street gift voucher.

What are the alternatives for treatment?

The current treatments for recurrent sore throat are tonsillectomy - to remove the palatine tonsils, or the use of over-the-counter pain killers and antibiotics that have been prescribed to you for short term relief of symptoms. The clinician together with you will decide which treatment is best for you and when a tonsillectomy is needed.

What are the possible disadvantages or risks of taking part?

The risks associated with participation in this study are the usual risks associated with a tonsillectomy or with standard non-surgical sore throat treatment (painkillers and/or antibiotics). Tonsillectomy is a painful procedure which requires an average of 14 days off work to recover. There is a small risk associated with the use of general anaesthetic. Complications from surgery, although very rare, can in some circumstances be life threatening. The risks associated with surgery can be discussed with your clinician at your referral visit. More information on adult tonsil surgery can be found at: https://entuk.org/docs/patient_info_leaflets/09001_adult_tonsil_surgery.

This study involves randomisation into one of two treatment groups. If you are not willing to undergo randomisation or would be very disappointed if you were allocated to one or the other intervention groups, please speak to your clinician or research nurse.

What are the side effects of any treatment that I will receive if I take part?

Side effects of a tonsillectomy include post-operative sore throat and in around 6% of patients, post-operative bleeding. Usually, but not always, this is minor, however even a minor bleed may require your return to hospital. Tonsillectomy can also cause changes in taste or tongue sensations.

Harm to the unborn child

To take part in the study, women must not be pregnant or breast feeding. Women of childbearing age randomised to receive immediate tonsillectomy must use adequate contraception during the time between randomisation and undergoing surgery. If you do become pregnant before you are due to have surgery, you must tell your doctor. The safety of anaesthetics in early pregnancy cannot be guaranteed.

What are the possible benefits of taking part?

The study will not benefit you directly; however the unique information from NATTINA will help improve the treatment of thousands of people with recurrent acute tonsillitis in the UK each year.

What happens when the research study stops?

When we have answers to the questions in the trial, whether that is at the end of the study or before, we will use the information to give all patients the best possible treatment.

Will my taking part in this study be kept confidential?

All study information, including personal details, will be kept confidential and will not be made public. With your permission, we will let your family doctor (GP) know that you are taking part.

Once you have consented to the study, your contact details (name, date of birth, address, email address, telephone number, mobile number and NHS number) will be sent to the Newcastle Clinical Trials Unit (NCTU). All your information will be safely stored at Newcastle University and used for the following purposes:

- The NCTU will use your name and address to send you the 6 monthly study questionnaires in the post to fill out at home.
- Your email address and mobile/telephone number will accessed by CI-Data - a responsible private company, in order for them to send you weekly sore throat alerts and STARs by your preferred method: text, email or telephone. Your details will be kept strictly confidential and will only be used by the company for this purpose and for the duration of your 24 month follow up.
- The NCTU will use your NHS number, date of birth and initials to access your GP records at the end of your 24 month follow up to collect information on the public health services used during the study. The NCTU will send these details by email or fax to your GP or to an individual associated with the research team who will arrange access to your GP records.

By signing the consent form, you are giving your permission for all the above to happen. Everyone involved in this study has a duty of confidentiality to the participants and this will be maintained.

The study data and your original medical records may be looked at by people who are monitoring or auditing the study, Independent Ethics Committee (IEC) or the hospital Trusts involved in the study, to make sure that the study is being run correctly.

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

If you are eligible for the NATTINA 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, an estimate of the number of sore throat days you experienced over the past and a short questionnaire about your quality of life.

You can also take part in an interview with a researcher from Newcastle University to discuss your views and experiences of sore throats and their treatments. If you would like more information or are interested in having an interview, please complete an expression of interest form with your contact details and hand this back to the research nurse. This will be returned to Newcastle University where a researcher will get in touch to discuss more about what is involved in the interview and to arrange an interview at a time and location convenient for you. Alternatively we can arrange an interview over the telephone. At the time of the interview, the researcher will ask you to give consent to allow Newcastle University to use data you give for research, which will be anonymised and your details will not be made public. As a gesture of thanks for taking part in an interview we will offer you a £15 voucher.

PART 2

What if relevant new information becomes available?

If during the course of the study new information becomes available, we will tell you about it and discuss whether you should or would like to withdraw from the study. If it is better for you to withdraw, you can do this without giving a reason. This will not affect the care that you receive.

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

You have the right to withdraw from the study at any time for any reason, and without giving a reason. We might ask if you are happy for us to record why you have decided to withdraw and will also keep the data we have collected on you up to the point of withdrawal.

Can I cross over from conservative management to tonsillectomy?

If you have been randomised to conservative management and at some point during the study you wish to be put forward for surgery, you will be able to cross over into the tonsillectomy group upon request if you still meet the NHS guidelines for surgery. Please contact the study team using the contact details at the end of this information sheet or the number on your contact card. Your clinician may ask you to attend a clinic visit to discuss your options with you and will arrange your surgery. You will not have to visit your GP again to be referred.

What if there is a problem?

If you have a concern about any aspect of this study you should ask to speak to the researcher who will do their best to answer your questions: (Insert Principal Investigator contact name and number here).

If something does go wrong and you are harmed in the course of this study, there are no special compensation arrangements. If you are harmed due to someone's negligence, you may have grounds for legal action against The Newcastle upon Tyne Hospitals NHS Foundation Trust, and the normal NHS complaints mechanisms are still available to you.
If you are still unhappy and wish to complain formally, you can do so through the hospital's procedure Patients Complaints Liaison Service (PALS) or Hospital Complaints Procedure – delete as appropriate for site specific): (Insert contact details here).

Involvement of the General Practitioner/family doctor (GP)

With your permission, we will let your family doctor (GP) know that you are taking part. Participation in the study will also be noted in your hospital records so that anyone who treats you will know you are taking part in the study.

With your consent, we will contact your GP at the end of your 24 month follow up visit to collect information about any visits you made to the GP, walk in clinics or A&E due to sore throats. This information will support the questionnaires, weekly alerts and STARs you complete.

Who is organising and funding the research?

This study is being funded by the NIHR Health Technology Assessment programme. This UK government scheme supports research for the benefit of the NHS and its patients. NATTINA is being organised by a team of researchers based in Newcastle upon Tyne, Dundee and Glasgow.

What will happen to the results of the research study?

The results of the research study will be published in medical journals, and will be sent to the funder as a report. They will be presented at medical conferences and shared with other doctors, nurses, as well as patients with recurrent acute tonsillitis. All study data in published articles are anonymous.

Once the study has finished, you will be able to access information about the results on the NATTINA website. Alternatively you can be informed about your contribution to the study upon request.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your interests. This study has been reviewed and given favourable opinion by (Insert ethics committee here).

Further information and contact details

If you have any further questions or would like more information about the study or the rights of participants, please feel free to contact us on the numbers below. These are also the contacts you or your doctor should use in the event of a study related emergency:

Study team contact number - (Insert name here and number here)
Out of hours emergency contact number – (insert number here)

Thank you for your interest in the study and for taking part, if you decide to do so.