

# The National Trial of Tonsillectomy in Adults

<b>Submission date</b> 30/07/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 04/08/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/01/2024	<b>Condition category</b> Ear, Nose and Throat	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

NATTINA is a clinical trial for adults with recurrent acute tonsillitis (inflammation of the tonsils) and is looking to establish the clinical and cost effectiveness of tonsillectomy (surgery to remove the tonsils) compared with conservative management (delayed surgery), which, through observation and statistical modelling of outcomes, will evaluate the impact of alternative sore throat patient pathways and develop future research. The study is split into 3 phases: feasibility, internal pilot and main trial. The feasibility study will explore patient, clinician and GP decision making of acute recurrent tonsillitis and will assess the practicality of the proposed NATTINA trial.

### Who can participate?

Patients aged 16 years and over who have been referred to secondary care with recurrent acute tonsillitis.

### What does the study involve?

The feasibility study involves in-depth interviews with tonsillitis patients, ENT staff and GPs which will explore patients' willingness to be randomised, as well as clinician/GP willingness to randomly allocate or refer patients. Interviews will also investigate acceptability of the conservative management treatment group and collate the views and experiences of sore throat and its treatment. The NATTINA internal pilot and main trial involves the randomisation of participants to either tonsillectomy or conservative management. Participants will be followed up for 24 months, during which the patient submits weekly sore throat information, completes 6 monthly questionnaires and attends 2 clinic visits.

### What are the possible benefits and risks of participating?

There may be no direct benefit for the patient but the information revealed from this study will help improve the treatment of people with recurrent acute tonsillitis. There are no risks associated with this study.

### Where is the study run from?

Newcastle University (UK)

When is the study starting and how long is it expected to run for?

The feasibility study will start in July 2014, the internal pilot in December 2014 and the main trial commencing in June 2015. The study is expected to last until June 2020.

Who is funding the study?

NIHR Health Technology Assessment (HTA) Programme (UK)

Who is the main contact?

Rebecca Wilson

Rebecca.wilson2@ncl.ac.uk

**Study website**

<http://research.ncl.ac.uk/nattina/>

## Contact information

**Type(s)**

Scientific

**Contact name**

Ms Rebecca Wilson

**Contact details**

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers**

16972, HTA 12/146/06

## Study information

**Scientific Title**

The NATional Trial of Tonsillectomy IN Adults: a clinical and cost effectiveness study

**Acronym**

NATTINA

## **Study objectives**

The NATTINA feasibility study will use qualitative and cognitive interviews to assess the practicality of the planned NATTINA internal pilot and full scale randomised controlled trial and will address any key issues raised, as well as evaluate the recruitment process, design and delivery of usual care, the experiences and acceptability of the treatments, acceptability of the questionnaire design and the outcome measures.

The NATTINA pilot and main trial will estimate treatment effectiveness based on number of sore throat episodes, sore throat severity, quality of life and number of primary/secondary healthcare interactions at baseline and throughout the patient's 24 month follow-up, which will help to model future patient sore throat pathways and provide more accurate guidelines for tonsillectomy referral. The study will also consider socio-economic aspects and estimate the efficiency to the NHS and patients.

More details can be found at: <http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=16972> and <http://www.nets.nihr.ac.uk/projects/hta/1214606>

Protocol can be found at: [http://www.nets.nihr.ac.uk/\\_\\_data/assets/pdf\\_file/0018/123354/PRO-12-146-06.pdf](http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0018/123354/PRO-12-146-06.pdf)

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Feasibility: 15/LO/1115; First MREC approval date 18/06/2014  
NATTINA: 14/NE/1144; First MREC approval date 10/11/2014

## **Study design**

Randomised controlled surgical trial

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Hospital

## **Study type(s)**

Treatment

## **Participant information sheet**

Available on the NATTINA website or upon request (contact details below)

## **Health condition(s) or problem(s) studied**

Topic: Ear, nose and throat; Subtopic: Ear (all Subtopics); Disease: Ear, nose & throat

## **Interventions**

### Feasibility study:

Qualitative Interviews - participants will have an in-depth interview with a researcher

Follow Up Length: 5 month(s)

### Main trial:

1. Conservative Management - usual care as normally treated by the patients themselves or the referring GP, comprising self-administered analgesia, +/- ad hoc primary care prescription of antibiotics. Patients are asked to defer surgery for up to 24 months, and reviewed at 12 months to assess their willingness to remain in conservative management arm
2. Immediate Tonsillectomy - immediate Tonsillectomy within 6-8 weeks of randomisation; Study Entry : Registration and One or More Randomisations

### Intervention Type

Procedure/Surgery

### Primary outcome measure

The number of sore throat days collected through weekly 'returns' from the participants over a period of 24 months will be the primary outcome measure. The data will allow comparison of tonsillectomy versus conservative management to determine the effectiveness in recurrent adult tonsillitis.

### Secondary outcome measures

1. Responses on the Tonsil Outcome Inventory 14 and STAR data to measure frequency, severity, health and economic impact of any sore throat episodes experienced.
2. Quality-of-life as recorded by SF-12 at the end of study follow up
3. Quality of life using SF-6D scores derived from the SF-12 responses measured at baseline, throughout the study and during episodes of sore throat experienced
4. The number of adverse events, visits to the GP/walk-in clinic/A&E, prescriptions issued and additional interventions required as collected from GP records and other primary care linkage data.
5. Incremental cost per sore throat day avoided from the perspective of the NHS and patients over 24 months to measure the cost effectiveness
6. The views and experiences of patients and clinicians regarding tonsillectomy and conservative management and how patient experience may shape any future research required

### Overall study start date

08/07/2014

### Completion date

24/06/2020

## Eligibility

### Key inclusion criteria

1. Age 16 years and over
2. Recurrent sore throats which fulfil current SIGN guidance for elective tonsillectomy.
3. Subject has provided written informed consent for participation in the study prior to any study specific procedures

ENT staff for the feasibility study interviews must be ENT staff members at a participating site and likely to be involved in the proposed NATTINA trial.

There are no exclusion criteria for GPs for the feasibility study.

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

16 Years

**Sex**

Both

**Target number of participants**

There will be 45 participants in the feasibility study, 72 in the internal pilot (over 6 months) and 528 in the main trial (18 month recruitment).

**Key exclusion criteria**

1. Under 16 years of age
2. Previous tonsillectomy
3. Listed directly (i.e. added to waiting list without prior elective ENT outpatient appointment) during emergency admission (e.g. due to peritonsillar abscess/quinsy)
4. Primary sleep breathing disorder
5. Suspected malignancy
6. Tonsilloliths
7. Pregnant or breastfeeding
8. Bleeding diathesis
9. Therapeutic anticoagulation
10. Inability to complete self-reported questionnaires and sore throat returns

There are no exclusion criteria for GPs or ENT staff for the feasibility study.

**Date of first enrolment**

08/07/2014

**Date of final enrolment**

30/04/2018

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Newcastle Clinical Trials Unit**  
Institute of Health and Society  
Newcastle University  
4th Floor William Leech Building  
Newcastle Upon Tyne  
United Kingdom  
NE2 4HH

## Sponsor information

### Organisation

Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

### Sponsor details

Leazes Wing  
Royal Victoria Infirmary  
Queen Victoria Road  
Newcastle Upon Tyne  
England  
United Kingdom  
NE1 4LP

### Sponsor type

Hospital/treatment centre

### Website

<http://www.newcastle-hospitals.org.uk/>

### ROR

<https://ror.org/05p40t847>

## Funder(s)

### Funder type

Government

### Funder Name

National Institute for Health Research

### Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### Funding Body Type

Government organisation

**Funding Body Subtype**  
National government

**Location**  
United Kingdom

## Results and Publications

### Publication and dissemination plan

It is planned to publish this study in peer review articles and to present data at national and international meetings. Results of the study will also be reported to the Sponsor and Funder, and will be available on their website. A lay summary of the study results will be made available to the participants on the NATTINA website at the end of the study.

**Intention to publish date**  
30/04/2021

### Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

**IPD sharing plan summary**  
Data sharing statement to be made available at a later date

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	06/06/2015		Yes	No
<a href="#">Results article</a>	version 1	17/05/2023	22/05/2023	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Plain English results</a>		13/07/2023	13/07/2023	No	Yes
<a href="#">Results article</a>		01/12/2023	11/01/2024	Yes	No