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The National Trial of Tonsillectomy in Adults

Submission date
30/07/2014

Recruitment status
No longer recruiting

Registration date
04/08/2014

Overall study status
Completed

Last Edited
11/01/2024

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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, acceptibility 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

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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Sex
All

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
United Kingdom

England

Study participating centre
Newcastle Clinical Trials Unit
Institute of Health and Society
Newcastle University
4th Floor William Leech Building
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Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust (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

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?
Results article		17/05/2023	22/05/2023	Yes	No
Results article		01/12/2023	11/01/2024	Yes	No
Protocol article	protocol	06/06/2015		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet version 1	11/11/2025	11/11/2025	No	Yes
Plain English results		13/07/2023	13/07/2023	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes