

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

Thank you very much for taking part in the NATTINA Study. Without your help and valuable time, we would not have been able to undertake the study.

NATTINA was carried out by a large team of people led by the Chief Investigator, Professor Janet Wilson. The study was sponsored by The Newcastle upon Tyne Hospitals NHS Foundation Trust and funded by the National Institute for Health and Care Research Health Technology Assessment Programme (NIHR HTA).

Many adult patients suffer with recurrent sore throats, due to tonsillitis. This may lead to loss of time at school or work. In severe cases, patients are admitted to hospital and may suffer from dangerous complications of the infection. A lack of studies led to the myth that tonsillectomy in adults was of limited value. This generated variation in the numbers of patients referred for tonsillectomy in different geographical areas. Some patients had to suffer with excessive rates of tonsillitis before being referred for tonsillectomy.

The aim of NATTINA was to investigate the effectiveness of tonsillectomies compared with taking painkillers or antibiotics (also called conservative management).

The study took place within 27 NHS trusts based throughout England and Scotland. The study started in April 2015 and completed in April 2020.

NATTINA included a Patient and Public Involvement group (PPI Group). This group included members of the public with experience of severe sore throats. The group helped the research team significantly by reviewing study documentation to ensure it was clear and providing advice regarding any changes needed throughout the study.

Who participated in the study?

The study included adults aged 16 years and over, who had been referred to an Ear, Nose and Throat (ENT) specialist to discuss treatment options for managing recurrent acute tonsillitis. The study recruited 453 participants.

What treatments did the participants receive?

Participants were randomised to receive either an immediate tonsillectomy (to be performed within 6-8 weeks of being randomised) or conservative management (following the usual care pathway of over-the-counter pain killers on a need to use basis, attendances to the GP for antibiotics or walk in clinics/A&E for more serious episodes).

What medical problems (adverse reactions) did the participants have?

The most common adverse events reported throughout the study were throat and/or ear pain. Other commonly reported adverse events included bleeding, infection, difficulty swallowing, nausea/vomiting and tiredness.

While re-admission to hospital was required for some participants for further treatment (in particular in relation to post-operative bleeding), none required a return the surgery.

What happened during the study?

Participants' involvement in the study lasted for 24 months. During this time all participants were asked to confirm on a weekly basis how many days they had suffered from a sore throat (this was done via text message, email, or a voice response via telephone). If they had experienced a sore throat that week, they were also asked to complete a questionnaire called the Sore Throat Alert Return (STAR) which asked for further details about the sore throat.

All participants were asked to complete a set of questionnaires on a regular basis about throat symptoms and quality of life (at the start of their study involvement and then at 6 months, 12 months, 18 months and 24 months – 5 times in total).

Those in the tonsillectomy group also received a phone call from a Research Nurse one week and two weeks after surgery to ask about any side effects and check on the participant's welfare.

What were the results of the study?

The NATTINA study showed that tonsillectomy is an effective intervention for adults with recurrent acute tonsillitis. It found that participants that had a tonsillectomy suffered significantly fewer sore throat days over the 24-months they were in the study compared with participants that were treated conservatively (i.e., using antibiotics and/or painkillers). Participants randomised to tonsillectomy experienced approximately half the number of days of sore throat over the 24-months than participants randomised to conservative management. This comparison included the 10 to 14 days of sore throat that would be expected after a tonsillectomy.

Participants who had a tonsillectomy also reported, on average, needing to contact healthcare professionals (such as their GP) less which meant they did not have to take as much time away from work and/or usual activities, in order to attend appointments in relation to sore throats/tonsillitis.

How has this study helped patients and researchers?

NATTINA has demonstrated definitively that tonsillectomy for recurrent acute tonsillitis is effective in reducing sore throats. This research provides health care professionals and patients with the information they need to help make an informed decision about whether an individual patient would wish to undergo tonsillectomy. For providers of healthcare, NATTINA has demonstrated that tonsillectomy in adults is cost effective. This should ensure that all patients who are suffering with recurrent tonsillitis have access to consider a tonsillectomy, in a timely manner.

Details of any further research planned:

NATTINA recruited patients who, at the time the trial was conducted, met the SIGN criteria for being offered a tonsillectomy: seven episodes of tonsillitis in a year, five episodes a year for two years, or three episodes a year for three years. These criteria were based on studies in young children from almost 40 years ago and were based on expert opinion rather than robust studies in adults. The SIGN criteria were withdrawn in 2020 after they were 10 years old. There is a need to update this guidance. Further work is planned, based on some of the NATTINA results, to develop evidence to support further guidance.

Where can I learn more about this study?

You can find out more information about the NATTINA study by visiting the study website: <u>https://research.ncl.ac.uk/nattina/</u>