

# NESTAC: North of England Study of Tonsillectomy and Adeno-tonsillectomy in Children

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|--|---|---|
| <b>Submission date</b><br>25/04/2003   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>25/04/2003 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>21/06/2010       | <b>Condition category</b><br>Ear, Nose and Throat | <input type="checkbox"/> Individual participant data  |

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

# Study information

## Scientific Title

## Acronym

NESTAC

## Study objectives

1. To investigate the clinical effectiveness of surgical intervention compared with non-surgical intervention in children under 16 with recurrent sore throat.
2. To investigate the relative costs and benefits of surgical and non-surgical interventions to the NHS and families.
3. To identify important outcomes for children and parents and to evaluate the impact on children's quality of life.
4. To investigate older children's and parents' preference for different treatment options.

Protocol can be found at <http://www.hta.ac.uk/protocols/199900200003.pdf>

More details can be found at <http://www.hta.ac.uk/1212>

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration.

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

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

Ear, nose and throat diseases

## Interventions

Please note that, as of 15 January 2008, the anticipated end date of this trial has been updated from 30 September 2006 to 31 August 2008.

**Interventions:**

Surgical intervention vs non-surgical intervention

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

The number of reported episodes of sore throat in the two years following date of randomisation.

**Secondary outcome measures**

1. The number of recorded episodes of sore throat from primary care practice records
2. Surgical and anaesthetic morbidity
3. Time off school
4. Parental time off work
5. Consumption of antibiotics and analgesics
6. Health-related quality of life
7. Child and parental satisfaction

**Overall study start date**

01/09/2001

**Completion date**

31/08/2008

**Eligibility**

**Key inclusion criteria**

Children <16 years with recurrent sore throat

**Participant type(s)**

Patient

**Age group**

Child

**Upper age limit**

16 Years

**Sex**

Both

**Target number of participants**

406

## **Key exclusion criteria**

Added 21/06/10:

1. Hospitalisation due to peritonsillar abscess (quinsy)
2. Obstructive symptoms suggestive of clinically significant sleep apnoea syndrome
3. Rare medical conditions such as glomerulonephritis or Henoch Schonlein purpura
4. Previous tonsillectomy
5. Suspected velopharyngeal insufficiency
6. Co-morbidity that means patient is unable to undergo surgery within the next six months
7. Bleeding disorders
8. Congenital/valvular heart disease

## **Date of first enrolment**

01/09/2001

## **Date of final enrolment**

31/08/2008

## **Locations**

### **Countries of recruitment**

England

United Kingdom

### **Study participating centre**

**Centre for Health Services Research**

Newcastle upon Tyne

United Kingdom

NE2 4AA

## **Sponsor information**

### **Organisation**

Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

### **Sponsor details**

Freeman Hospital

Freeman Road

High Heaton

Newcastle upon Tyne

England

United Kingdom

NE7 7DN

+44 (0)191 233 6161

**Sponsor type**

Hospital/treatment centre

**Website**

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

**ROR**

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

## Funder(s)

**Funder type**

Government

**Funder Name**

NIHR Health Technology Assessment Programme - HTA (UK)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

| Output type                      | Details  | Date created | Date added | Peer reviewed? | Patient-facing? |
|----------------------------------|----------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol article</a> | protocol | 09/08/2006   |            | Yes            | No              |
| <a href="#">Results article</a>  | results  | 01/03/2010   |            | Yes            | No              |