

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

Submission date 25/04/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 25/04/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/06/2010	Condition category 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

Contact name
Prof John Bond

Contact details
Centre for Health Services Research
University of Newcastle upon Tyne
21 Claremont Place
Newcastle upon Tyne
United Kingdom
NE2 4AA
+44 (0)191 222 6777
john.bond@newcastle.ac.uk

Additional identifiers

Protocol serial number
HTA 99/20/03

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

Completion date

31/08/2008

Eligibility**Key inclusion criteria**

Children <16 years with recurrent sore throat

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Upper age limit

16 years

Sex

All

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

United Kingdom

England

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)

ROR

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

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

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?
	results				

Results article		01/03/2010	Yes	No
Protocol article	protocol	09/08/2006	Yes	No