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

Submission date 25/04/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/04/2003	**Overall study status** Completed	
Last Edited 21/06/2010	**Condition category** Ear, Nose and Throat	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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.

Primary study design
Interventional

Study design
Randomised controlled trial

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