

The effectiveness of adenotonsillectomy in children

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Registration date 02/05/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/10/2009	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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
NTR940

Study information

Scientific Title

The effectiveness of adenotonsillectomy in children NATAN project: Nederlands AdenoTonsillectomie project, Tonsillectomy & Adenoidectomy in the Netherlands

Acronym

NATAN

Study objectives

Adenotonsillectomy in children with mild to moderate symptoms of throat infections or adenotonsillar hypertrophy prevents upper airway infections and fever episodes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Medical Ethical Committee on the 10th January 2000 (ref: 99-49).

Study design

Randomised, active controlled, parallel group, multicentre 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

Throat infections, Adenotonsillectomy, Adenotonsillar hypertrophy

Interventions

Interventions are adenotonsillectomy within six weeks versus watchful waiting.

During the study, the child's temperature was measured daily with a validated infrared tympanic membrane thermometer with an electronic device built in that stored the date and first temperature measurement of each day. Thermometer data were collected by the study physician during scheduled follow-up visits at 3, 6, 12, 18 and 24 months.

During the study, parents kept a diary of complaints of upper respiratory infections in their child, i.e., sore throat, pain/difficulty at swallowing, cough, rhinorrhoea, earache and otorrhoea. They also noted absence from day-care or school due to upper respiratory infections, and resource

use such as prescription and over the counter medication, out-patient visits, additional surgical interventions and out-of-pocket expenses such as babysitters and travel expenses.

Diary data were collected by the study physician during scheduled follow-up visits at 3, 6, 12, 18 and 24 months. On the basis of these data incidences of throat infections, sore throat, upper respiratory infections, absence from day-care or school due to upper respiratory infections and costs were calculated.

At inclusion and the scheduled follow-up visits at 3, 6, 12, 18 and 24 months disease-specific and health-related quality of life questionnaires (43-item TNO-AZL Preschool children Quality of Life [TAPQoL], 56-item TNO-AZL Child Quality of Life [TACQoL], and Child Health Questionnaire - Parent Form 50 [CHQ-PF50]) were filled out. An ear, nose and throat examination was performed including tympanometry and length and weight were measured. These data were used to establish the effect of adenotonsillectomy on middle ear status, sleeping and eating pattern, length and weight and health-related quality of life.

Serum samples were collected at baseline and at one-year follow-up to evaluate changes in serum immunoglobulin levels in relation to surgery and occurrence of Upper Respiratory Infections (URIs).

Oropharyngeal swabs were taken at baseline and at 3 and 12 months follow-up to study the effect of adenotonsillectomy on carriage of potential pathogenic bacteria in the oropharynx at 3 and 12 months follow-up and the association between carriage of these potential pathogens and the number of throat infections during the 12 months follow-up.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Incidence of fever (a temperature of 38.0°C or higher) for at least one day, measured in number of episodes and days. An episode was considered finished when at least one day was without fever. New episodes were those occurring after a fever-free interval of at least seven days.

Secondary outcome measures

Secondary outcome measures were:

1. Throat infections
2. Sore throat days and episodes
3. Upper respiratory infections
4. Otitis media
5. Sleeping and eating pattern
6. Length and weight
7. Absence from day-care or school due to upper respiratory infections
8. Health-related quality of life
9. Costs
10. Immunological parameters
11. Oropharyngeal microbial flora

Secondary outcomes were measured during follow-up visits at 3, 6, 12, 18 and 24 months.

Overall study start date

01/03/2000

Completion date

01/02/2003

Eligibility

Key inclusion criteria

Children aged 2 to 8 years indicated for adenotonsillectomy according to current medical practice. These included children with recurrent throat infections (three or more episodes per year) or other indications such as obstructive complaints or recurrent upper respiratory infections.

Participant type(s)

Patient

Age group

Child

Lower age limit

2 Years

Upper age limit

8 Years

Sex

Not Specified

Target number of participants

300

Key exclusion criteria

Children with:

1. A history of seven or more throat infections in the preceding year, or five or more in each of the two preceding years, or three or more in each of the three preceding years (Paradise criteria)
2. High suspicion of obstructive sleep apnoea, i.e. Brouillette's Obstructive Sleep Apnoea (OSA) score of more than 3.5
3. Down's syndrome
4. Craniofacial malformation, such as cleft palate
5. Documented immunodeficiency, other than Immunoglobulin A (IgA) or Immunoglobulin G subclass two (IgG2) deficiencies

Date of first enrolment

01/03/2000

Date of final enrolment

01/02/2003

Locations

Countries of recruitment

Netherlands

Study participating centre

University Medical Centre Utrecht

Utrecht

Netherlands

3508 AB

Sponsor information

Organisation

University Medical Centre Utrecht (UMCU) (Netherlands)

Sponsor details

P.O. Box 85500

Utrecht

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3508 GA

Sponsor type

Hospital/treatment centre

Website

<http://www.umcutrecht.nl/zorg/>

ROR

<https://ror.org/04pp8hn57>

Funder(s)

Funder type

Government

Funder Name

The Dutch Health Care Insurance Board (CVZ) (Netherlands) - knowledge development programme (programma Ontwikkelingsgeneekunde)

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?
Results article	results	18/09/2004		Yes	No
Results article	results	01/11/2007		Yes	No
Results article	results	01/10/2009		Yes	No