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The effectiveness of adenotonsillectomy in children

Submission date	Recruitment status	[_] Prospectively registered
02/05/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/05/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/10/2009	Infections and Infestations	

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 adenenotonsillar 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
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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