The effectiveness of adenotonsillectomy in children.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26888

Source
Nationaal Trial Register

Brief title
NATAN

Health condition

1. Throat infections;

2. adenenotonsillar hypertrophy;

3. adenotonsillectomy.

Sponsors and support

Primary sponsor: University Medical Center Utrecht
PO box 85500
3508 GA Utrecht
The Netherlands
Source(s) of monetary or material Support: CVZ programma Ontwikkelingsgeneekunde projectnr OG 99-060

Intervention

Outcome measures

Primary outcome

Incidence of fever episodes defined as a body-temperature of 38.0 C or higher for at least one day.

Secondary outcome

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.

Study description

Background summary

Objective:

In the Netherlands children with recurrent mild to moderate symptoms of throat infections or adenotonsillar hypertrophy may ultimately undergo adenotonsillectomy. Evidence regarding the balance between costs and effects of this specific ‘low threshold’ practice is lacking. A randomized design was used to evaluate the cost-effectiveness of adenotonsillectomy compared to watchful waiting.

Design:

Economic evaluation alongside an open randomised controlled trial.

Setting:

Multi-center: 21 general and 3 university hospitals in the Netherlands.

Participants:

300 children, aged 2 to 8 years selected for adenotonsillectomy according to routine medical practice. Excluded were children with very frequent throat infections and those with suspected obstructive sleep apnoea.

Intervention:

Adenotonsillectomy versus watchful waiting.
Main outcome measures: Incremental cost-effectiveness in terms of costs per fever episode avoided, per throat infection avoided and per upper respiratory tract infection avoided.

Results:

Annual costs incurred in the adenotonsillectomy group amounted to €803 and €551 in the watchful waiting group (46% increase). During a median follow-up period of 22 months, surgery as compared to watchful waiting reduced the number of fever episodes and throat infections by 0.21 per person year (95% confidence intervals -0.12 to 0.54 and 0.06 to 0.36, respectively), and upper respiratory tract infections by 0.53 (95% confidence interval 0.08 to 0.97) episodes. The incremental cost per episode avoided were €1,136, €1,187 and €465 respectively.
Conclusion: For children undergoing adenotonsillectomy for mild to moderate symptoms of throat infections or adenotonsillar hypertrophy the operation resulted in a significant increase in costs without realising relevant clinical benefit. Subgroups of children for whom surgery would be cost-effective may be identified in further research.

Study objective

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

Study design

N/A

Intervention

Adenotonsillectomy within 6 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, rhinorrhea, earache and otorrhea. 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 (TAPQoL, TACQoL, and CHQpf50) 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 1 year follow-up to evaluate changes in serum immunoglobulin levels in relation to surgery and occurrence of 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.

Contacts

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Eligibility criteria

Inclusion criteria

Children aged 2 to 8 years indicated for adenotonsillectomy according to current medical practice. These included children with recurrent throat infections (3 or more episodes per year) or other indications such as obstructive complaints or recurrent upper respiratory infections.

Exclusion criteria

Children with:

1. A history of 7 or more throat infections in the preceding year, or 5 or more in each of the two preceding years, or 3 or more in each of the 3 preceding years (Paradise criteria);

2. High suspicion of obstructive sleep apnoea, i.e. Brouillette¡¦s OSA-score of more than 3.5;

3. Down¡¦s syndrome;

4. Craniofacial malformation, such as cleft palate;

5. Documented immunodeficiency, other than IgA or IgG2 deficiencies.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2000
Enrollment:	300
Type:	Actual

Ethics review

Positive opinion

Date:	26-03-2007
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL916
NTR-old	NTR940
Other	:
ISRCTN	ISRCTN04973569

Study results

Summary results

1. van Staaij BK, van den Akker EH, Rovers MM, Hordijk GJ, Hoes AW, Schilder AG. Effectiveness of adenotonsillectomy in children with mild symptoms of throat infections or adenotonsillar hypertrophy: open, randomised controlled trial.
BMJ. 2004 Sep 18;329(7467):651.
2. Arch Otolaryngol Head Neck Surg. 2007 Nov;133(11):1083-8.
