

Effectiveness of adenoidectomy in children with recurrent upper respiratory tract infections.

No registrations found.

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

Summary

ID

NL-OMON20709

Source

NTR

Brief title

NOA (Nederlands Onderzoek Adenotomie)

Health condition

English: Adenoidectomy, Upper respiratory tract infection, Common cold, Rhinosinusitis, Child, Randomised controlled trial

Dutch: Adenotomie, Bovenste luchtweginfectie, Verkoudheid, Rhinosinusitis, Kind

Sponsors and support

Primary sponsor: University Medical Centre Utrecht
The Netherlands

Source(s) of monetary or material Support: ZonMw Health Care Efficiency Research, approved 2006
number: 80-007022-98-07901

Intervention

Outcome measures

Primary outcome

Upper respiratory tract infection with or without fever (38°C or higher)

Secondary outcome

1. Acute otitis media and otitis media with effusion episodes;
2. Exhaled nitric oxide;
3. Nasopharyngeal flora;
4. Health related quality of life;
5. Cost-effectiveness

Study description

Background summary

Background: Convincing evidence regarding the effectiveness of adenoidectomy in children with recurrent upper respiratory tract infections is lacking.

Aim: to determine the effectiveness of adenoidectomy in children with recurrent upper respiratory tract infections.

Study design: multi-centre randomized controlled trial.

Study population: 110 children aged 1-6 years selected for adenoidectomy primarily because of recurrent upper respiratory tract infections (common colds and rhinosinusitis).

Intervention: adenoidectomy within 6 weeks versus a watchful waiting strategy.

Follow-up: 2 years including symptom diaries, daily temperature measurements and follow-up visits at 3, 6, 12, 18 and 24 months.

Primary outcome: upper respiratory tract infections with or without fever (38°C or higher).

Secondary outcome: episodes of acute otitis media and otitis media with effusion, nasopharyngeal flora, exhaled nitric oxide, health related quality of life, cost-effectiveness.

Study objective

This is a superiority trial testing the hypothesis that adenoidectomy is more effective than a watchful waiting strategy in children with recurrent upper respiratory tract infections.

Intervention

Adenoidectomy within 6 weeks versus watchful waiting.

Contacts

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Eligibility criteria

Inclusion criteria

Children aged 1-6 years selected for adenoidectomy primarily because of recurrent upper respiratory tract infections (common colds and rhinosinusitis).

Exclusion criteria

1. Age younger than 1 year or older than 6 years;
2. Previous adenoidectomy or adenotonsillectomy;
3. Tympanostomy tubes present;
4. Selected for adenoidectomy combined with tympanostomy tubes;
5. Down's syndrome;
6. Craniofacial malformations (eg.cleft lip or palate)

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2007
Enrollment:	110
Type:	Actual

Ethics review

Positive opinion	
Date:	10-05-2007
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	NL943
NTR-old	NTR968

Register

Other
ISRCTN

ID

:
ISRCTN03720485

Study results

Summary results

none