Effectiveness of adenoidectomy in children with recurrent upper respiratory tract infections

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To establish: 1) the effectiveness of adenoidectomy compared to a non-surgical strategy in children in terms of reduction of upper respiratory tract infections (with or without fever) and improvement in quality of life 2) the costs-effectiveness of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON30729

Source
ToetsingOnline

Brief title
Adenoidectomy in children

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym
common cold, rhinosinusitis, upper respiratory tract infection

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: ZONMw programma doelmatigheid

Intervention

Keyword: adenoidectomy, child, cost-effectiveness, upper respiratory tract infection

Outcome measures

Primary outcome

Upper respiratory tract infections including common colds and episodes of

rhinosinusitis, with or without fever.

Secondary outcome

Health-related quality of life.

Study description

Background summary

Adenoidectomy is one of the most common operations in children in Western countries. With 24,450 adenoidectomies carried out as a primary procedure in 2002, it is the third most common operation in children in the Netherlands. Remarkably, the surgical rate in the Netherlands exceeds that in most other Western countries. Whereas in our country the main indication for adenoidectomy is recurrent upper respiratory tract infections, i.e. common colds or episodes of rhinosinusitis, in other countries most adenoidectomies are carried out for otitis media and upper airway obstruction. Convincing evidence regarding the effectiveness of adenoidectomy in children with upper respiratory tract infections is lacking.

Study objective

To establish:
1) the effectiveness of adenoidectomy compared to a non-surgical strategy in children in terms of reduction of upper respiratory tract infections (with or without fever) and improvement in quality of life
2) the costs-effectiveness of this procedure.

Study design

Multi-center randomized controlled trial.
Follow-up will be 2 years including symptom diaries and daily temperature

measurements and scheduled follow-up visits at 3, 6, 12, 18 and 24 months.

Intervention

Adenoidectomy within 6 weeks versus a non-surgical watchful waiting strategy.

Study burden and risks

Burden:
1 inclusion visit of 90 minutes at the participant's home, 5 follow-up visits of 45 minutes at the practice of the local ENT-surgeon, 19 telephone contacts of 10 minutes.

Risk:
Participants allocated to the adenoidectomy group carry the usual risks associated with this operation (haemorrhage, aspiration, nausea, fever). Participants allocated to the watchful waiting group carry the risk of persistence or progression of their symptoms of upper respiratory tract infections. Their parents are advised both in the information brochure and at the follow-up visits to contact their general practitioner and/or local ENT surgeon if symptoms grow worse. If both the doctor and parents agree that adenoidectomy is indicated, they are free to have this operation performed.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

-age 1-8 years
-selected for adenoidectomy in current ENT practice because of recurrent upper respiratory tract infections

Exclusion criteria

-children selected for adenoidectomy primarily because of ear related symptoms or symptoms of upper airway obstruction
-children selected for a combined procedure including adenoidectomy and insertion of tympanostomy tubes
-Down syndrome
-craniofacial malformations
-immunodeficiencies

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-04-2007
Enrollment:	110
Type:	Actual

Ethics review

Approved WMO Date:	03-10-2006
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-02-2007
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	15-01-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL14149.041.06