

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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20709

Bron

Nationaal Trial Register

Verkorte titel

NOA (Nederlands Onderzoek Adenotomie)

Aandoening

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

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

Ondersteuning

Primaire sponsor: University Medical Centre Utrecht
The Netherlands

Overige ondersteuning: ZonMw Health Care Efficiency Research, approved 2006
number: 80-007022-98-07901

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

Adenoidectomy within 6 weeks versus watchful waiting.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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)

Onderzoeksoepzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-04-2007
Aantal proefpersonen:	110
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	10-05-2007
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL943
NTR-old	NTR968

Register

Ander register
ISRCTN

ID

:
ISRCTN03720485

Resultaten

Samenvatting resultaten

none