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Effectiveness of adenoidectomy in children with recurrent upper respiratory tract infections

Submission date	Recruitment status	[_] Prospectively registered
30/05/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/05/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/01/2013	Surgery	

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
N/A

Study information

Scientific Title

Acronym
NOA (Nederlands Onderzoek Adenotomie)

Study objectives
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.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Medical Ethical Committee UMC Utrecht on the 13th October 2006 (ref: NL14149.041.06).

Study design
Randomised, multicentre, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Adenoidectomy in children, common cold, upper respiratory tract infection, rhinosinusitis

Interventions
Adenoidectomy within six weeks versus watchful waiting.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Upper respiratory tract infection with or without fever (38°C or higher); this will be measured continuously by means of symptom diaries and daily temperature measurements.

Secondary outcome measures
1. Acute otitis media and otitis media with effusion episodes, measured continuously by means of symptom diaries
2. Health related quality of life, measured at inclusion (0 months), 3 months, 12 months and 24 months follow-up
3. Cost-effectiveness, measured continuously by means of symptom diaries
4. Nasopharyngeal flora, investigated at inclusion (0 months), 3 months and 12 months follow-up
5. Exhaled nitric oxide, measured at inclusion (0 months), 3 months, 12 months and 24 months follow-up

Overall study start date
01/04/2007

Completion date
01/02/2010

Eligibility

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

Participant type(s)
Patient

Age group
Child

Lower age limit
1 Years

Upper age limit
6 Years

Sex
Not Specified

Target number of participants
110

Key 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. Downs syndrome
6. Craniofacial malformations (e.g. cleft lip or palate)

Date of first enrolment
01/04/2007

Date of final enrolment
01/02/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Centre Utrecht (UMCU)
Utrecht
Netherlands
3508 AB

Sponsor information

Organisation
University Medical Centre Utrecht (UMCU) (The Netherlands)

Sponsor details
P.O. Box 85500
Utrecht
Netherlands
3508 GA

Sponsor type
Hospital/treatment centre

Website
http://www.umcutrecht.nl/zorg/#http://www.umcutrecht.nl/zorg/

ROR
https://ror.org/04pp8hn57

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

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?
Thesis results	results	01/12/2012		No	No
Other publications	economic evaluation	01/02/2013		Yes	No