

Effectiveness of adenoidectomy in children with recurrent upper respiratory tract infections

Submission date 30/05/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/05/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/01/2013	Condition category Surgery	<input type="checkbox"/> Individual participant data

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