

Otitis media with effusion-effusion study

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Which mediators of inflammation and which factors of gastro-oesophageal reflux are present in middle ear effusion? Can the findings of this study attribute to pharmacological treatment of OME.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Middle ear disorders (excl congenital)
Study type	Observational non invasive

Summary

ID

NL-OMON35421

Source

ToetsingOnline

Brief title

OME-effusion

Condition

- Middle ear disorders (excl congenital)

Synonym

otitis media with effusion / glue-ear

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Heinsius-Houbolt Fonds

Intervention

Keyword: Gastro-esophageal reflux disease, Middle ear mucosa, OME

Outcome measures

Primary outcome

Analysis of middle ear effusion for mediators of inflammation and factors of gastro-oesophageal reflux.

Secondary outcome

NA

Study description

Background summary

Otitis media with effusion (OME) is one of the most common diseases in children. The duration of OME can vary. In persistent OME the hearing loss can result in an impaired development of speech, language, communicative and cognitive skills and parent-child interactions.

The pathogenesis of OME is multifactorial. Hypoventilation of the middle ear plays a central role. It seems that upper airway infections, allergy and gastro-oesophageal reflux are also involved.

The treatment of OME consists of watchful waiting or surgery with the placement of ventilation tubes. Ventilation tubes result in an alternative way of middle ear ventilation with resolution of the effusion from the middle ear, placement of ventilation tubes does not cure the primary cause. There is considerable disagreement about the indication for placement of ventilation tubes. Nevertheless, each year about 50.000 children are treated with ventilation tubes, with substantial regional differences.

Therefore, there is a clear indication for further research into which factors are involved in the chronic inflammatory reactions in the middle ear mucosa, attributing to the production of mucus. This research can improve the indication for treating OME with ventilation tubes, with pharmacological treatment as a possible alternative.

Study objective

Which mediators of inflammation and which factors of gastro-oesophageal reflux are present in middle ear effusion? Can the findings of this study attribute to pharmacological treatment of OME.

Study design

Before placement of a ventilation tube the effusion is evacuated from the middle ear and collected. The effusions are analysed for acidity, bacteriology, mediators of inflammation and factors of gastro-oesophageal reflux.

Study burden and risks

Collection of middle ear fluid takes a few minutes only. The surgical procedure is hardly lengthened, there are no risks and the post-operative course is not affected.

Contacts

Public

Academisch Medisch Centrum

Meibergdreef 9
1100 DD Amsterdam
NL

Scientific

Academisch Medisch Centrum

Meibergdreef 9
1100 DD Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

otitis media with effusion

Exclusion criteria

cleft palate
Down syndrome
immunological disorders

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 08-08-2012

Enrollment: 15

Type: Actual

Ethics review

Approved WMO

Date: 12-06-2012

Application type: First submission

Review commission: METC Amsterdam UMC

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	NL37924.018.11