Thorough clinical investigation of the host-pathogen interaction in chronic and recurrent otitis media.

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PROPOSAL PART I - TYMPANOSTOMY TUBE INSERTION Objective: Regarding children suffering from Acute or Chronic Otitis Media:Are there biological markers present in blood (and middle ear fluid), which will inform us about:1. The risk of recurrent...

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

Summary

ID

NL-OMON32359

Source
ToetsingOnline

Brief title
Host-Pathogen interaction in chronic and recurrent otitis media.

Condition

- Middle ear disorders (excl congenital)
- Hepatobiliary neoplasms malignant and unspecified

Synonym
middle ear infection, otitis media

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: bacterial and viral pathogens, host immune response, otitis media, transcriptomics

Outcome measures

Primary outcome

PROPOSAL PART I - TYMPANOSTOMY TUBE INSERTION

Determination of molecular and cellular immune response in relation to the

viral and bacterial pathogens causing otitis media.

PROPOSAL PART II - BIOFILM FORMATION

Gene expression profiling of the three major bacterial pathogens: S.

pneumoniae, H. influenzae and

M. catarrhalis present in biofilm, in comparison to in vitro cultures or middle

ear fluid.

Secondary outcome

PROPOSAL PART I - TYMPANOSTOMY TUBE INSERTION

Otitis Media Demography.

Viral and Bacterial Pathogen detection.

Gene expression profiling of the three major bacterial pathogens: S.

pneumoniae, H. influenzae and M. catarrhalis.

PROPOSAL PART II - BIOFILM FORMATION

Otitis Media Demography.

Viral and Bacterial Pathogen detection.

Study description

Background summary

Otitis Media (OM) is one of the most frequent diseases in childhood and the primary reason for children to visit a physician (1;2). In many countries it is the most common reason to prescribe antibiotics (3;4), or to undergo surgery (5). Costs for general health care are expanding, and are estimated to be 3-5 billion dollar anually in the United States (2;6-8).
Although OM management has no universal standard yet, it may imply watchful waiting, antibiotic treatment, adenoidectomy, insertion of tympanostomy tubes or vaccination. Approximately 80% of the acute otitis media (AOM) cases is self-limiting within 2-14 days and also otitis media with effusion (OME) resolves spontaneously: 60% of newly detected OME resolves within 3 months (9). However, in a part of the OM population persistent or recurrent episodes of OM are responsible for a significant morbidity for both children and parents, despite variable treatment options (10).
Through the set up of a new prospective cohort and investigation in a clinical setting, relevant patient characteristics, the role of bacterial and viral pathogens, the role of recurrent infection in relation to biofilm formation, and the host response at protein level will be studied in detail. This project is expected to increase the understanding of the underlying mechanisms of OM disease, and to support future treatment and prevention strategies. Towards a rational, multi valent vaccine development a better understanding in OM pathogenesis is warranted.

Study objective

PROPOSAL PART I - TYMPANOSTOMY TUBE INSERTION
Objective: Regarding children suffering from Acute or Chronic Otitis Media:
Are there biological markers present in blood (and middle ear fluid), which will inform us about:
1. The risk of recurrent infection
2. The severity of disease

PROPOSAL PART II - BIOFILM FORMATION
Objective: Regarding children suffering from Acute or Chronic Otitis Media:
Are there biological markers present in middle ear biofilm related pathogens, which will inform us about:
1. The severity of disease (virulence factors)
2. The risk of recurrent infection

Study design

PROPOSAL PART I - TYMPANOSTOMY TUBE INSERTION

Setting Radboud University Nijmegen Medical Centre, Nijmegen
Canisius Wilhelmina Hospital, Nijmegen
Study Period 01-11-2007 to 01-09-2009
Samples Questionnaire, Blood sample, Middle ear fluid,
Nasopharyngeal swab
Analyses At study entry and after 2-3 months :
1. Questionnaire: risk factors
2. Blood : FACS analysis, Proteomics,
Transcriptomics,
3. Nasopharyngeal swab: Bacterial culture,
Bacterial PCR, viral multiplex PCR.
4. Only at study entry: Middle ear fluid:
Bacterial Culture, Bacterial (rt)-PCR, Viral multiplex PCR,
FACS analysis.

PROPOSAL PART II - BIOFILM FORMATION
Setting Radboud University Nijmegen Medical Centre,
Nijmegen Canisius Wilhelmina Hospital, Nijmegen
Study Period 01-11-2007 to 01-09-2009
Samples At study entry:Middle Ear Mucosa biopsy or Old
Tympanostomy tubes
At study entry and after 2-3
months:Nasopharyngeal swab
Analyses Culture, (rt)-PCR, SE Microscopy, RT-(rt) PCR, Therapy
resistance

Study burden and risks

Burden

PROPOSAL PART I - TYMPANOSTOMY TUBE INSERTION
2x Questionnaire
2x Blood sample
2x Nasopharyngeal swab
1x Collection of middle ear fluid during surgical insertion of tympanostomy
tubes

PROPOSAL PART II - BIOFILM FORMATION
2x Questionnaire
2x Nasopharyngeal swab
1x Collection of 3 biopsy specimens during surgical debridement of the middle
ear.

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

I.
- Patients 0-5yrs old, seen at the Out Patient Department of ENT-surgery by an ENT-specialist in the UMC St Radboud or Canius Wilhelmina Hospital with...
- Episodes of recurrent Acute Otitis Media (rAOM) OR Chronic Otitis Media with Effusion (COME) OR Chronic Suppurative Otitis Media (CSOM) AND
- Who will receive tympanostomy tubes.
II.
- Patients 0-16 yrs of age, seen at the Out Patient Department of ENT-surgery by an ENT-specialist in the UMC St Radboud or the Canisius Wilhelmina Hospital with...
- Episodes of recurrent Acute Otitis Media (rAOM) OR Chronic Otitis Media with Effusion (COME) OR Chronic Suppurative Otitis Media (CSOM) AND...

- who will undergo middle ear clean up surgery.

Exclusion criteria

- no informed consent
- age category other than 0-5 years
- malignancies, organ transplantation in history, recent ear surgery e.g. mastoidectomy or cochlear implant (<2weeks ago)
- immunodeficiency
- current systemic infectious diseases (e.g. chickenpox, hepatitis)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2007
Enrollment:	1093
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL19892.091.07