

The correlation between culture of the nasopharyngeal swab, the nose swab, swab from a handkerchief and a handkerchief directly in children with an upper respiratory tract infection

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The objective is determine the correlation between the outcome of the cultures of the nasopharyngeal swab, the nose swab, the swab from a handkerchief and the handkerchief.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON36370

Source

ToetsingOnline

Brief title

The Runny Nose study

Condition

- Bacterial infectious disorders
- Respiratory tract infections

Synonym

common cold; upper respiratory tract infection

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: microbiology, nasal swab, nasopharyngeal swab, upper respiratory tract infection

Outcome measures

Primary outcome

The concordance and discordance between the culture results of the different sampling methods.

Secondary outcome

The differences in the observational Visual Analogue Scale scores between the different sampling methods.

Study description

Background summary

The nasopharyngeal swab is the gold standard for culturing pathogens involved in upper respiratory tract infections. Since children may experience this method as unpleasant (especially when performed repeatedly), we will study the accuracy of alternative culturing methods. We hope that the results of this study will allow us to replace the nasopharyngeal culture by one of the less unpleasant alternatives.

Study objective

The objective is determine the correlation between the outcome of the cultures of the nasopharyngeal swab, the nose swab, the swab from a handkerchief and the handkerchief.

Study design

A cross sectional study, during 6 months. The culture methods in randomized order are: 1. nasal swab, 2. blowing/whiping the nose, swab of the handkerchief

3. blowing/whipping of the nose, culture from handkerchief directly, 4. nasopharyngeal swab. Bacterial cultures for *S. pneumoniae* (including serotyping), *H. influenzae*, *M. catarrhalis* and *S. aureus* will be performed. Parents will fill in a short questionnaire and an observational Visual Analogue Scale.

Study burden and risks

We believe that the risk of this study is negligible, for the gold standard is generally accepted as safe and we plan on testing additional and even less unpleasant methods in parallel. The nasopharyngeal swab can give an unpleasant tickly feeling, cough and watery eyes. In rare cases a nose bleed can occur. Especially when the nasopharyngeal swab is taken repeatedly, the child may find this unpleasant. For this study only one nasopharyngeal swab has to be taken. This study is necessary to be able to replace the nasopharyngeal swab in the future for a reliable and well accepted test.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

- age 0 - 4 years
- a runny nose as a symptom of an upper respiratory tract infection

Exclusion criteria

- age 4 years and older
- antimicrobial therapy in the last 2 weeks
- earlier participation in this study
- medical conditions preventing the child from attending a regular day care centre
- craniofacial abnormalities and cleft palate

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 21-04-2010

Enrollment: 66

Type: Actual

Ethics review

Approved WMO

Date: 08-03-2010

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	04-06-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	27-05-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL30885.041.09