# Colonization and infection of the respiratory tract by Mycoplasma pneumoniae in children

Published: 06-05-2008
Last updated: 11-05-2024

Aims: 1. To optimize the diagnosis of M. pneumoniae infections by discriminating between colonization and symptomatic infection using quantitative PCR. 2. To study the role of host factors (age, and bacterial and viral co-infection) on infection by...

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Respiratory tract infections |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON35170

**Source**
ToetsingOnline

**Brief title**
MymIC

### Condition

- Respiratory tract infections

**Synonym**
common cold, Respiratory tract infection

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** children, colonization, Mycoplasma pneumoniae, respiratory tract infection

## Outcome measures

### Primary outcome

In this explorative study, M. pneumoniae will be quantified in nose- and throat swabs/aspirates of children aged 0-16 years with mild to severe symptoms of respiratory tract infection, and in a control group consisting of children without respiratory tract infection. The quantity of M. pneumoniae (in copies/ml or copies/swab) will be related to clinical disease in order to differentiate asymptomatic carriership from infection. To investigate the role of co-colonization or -infection, the presence of other bacteria or viruses in the respiratory tract will be analyzed as well. To study the age distribution in relation to M. pneumoniae infection, a precalculated number of patients of either < 5 or >= 5 years of age will be included. Genotyping of M. pneumoniae will be performed, and related to severity of disease and/or colonization. Prevalence of colonization and/or infection with M. pneumoniae will be calculated.

### Secondary outcome

Not applicable

# Study description

### Background summary

Background: 150 million children/year suffer from pneumonia worldwide, and 20 million children have to be hospitalized for this reason. Up to 40% of

community-acquired pneumonias are caused by Mycoplasma pneumoniae and as many as 34% of cases requiring hospitalization in children. Studies using the recently introduced PCR suggest that M. pneumoniae frequently causes respiratory tract infections (RTI), not only in older children as previously thought, but also in children younger than 5 years. This is important because M. pneumoniae is not sensitive to the first choice β-lactam antibiotics. Moreover, it is unknown whether the detection of M. pneumoniae by PCR also confirms this pathogen as the cause of the infection. A limited number of studies suggest that an asymptomatic carrier state exists. Due to the shortcomings in diagnosis, knowledge on the role of different host and bacterial factors on progression to infection is very limited.
Hypothesis
M. pneumoniae is capable of asymptomatic colonization, which can be differentiated from infection by quantitative PCR. M. pneumoniae causes RTI*s in children younger than 5 years as frequently as in older children. The genetic background of M. pneumoniae strains as well as viral co-infections influence progression from colonization to infection.

### Study objective

Aims:
1. To optimize the diagnosis of M. pneumoniae infections by discriminating between colonization and symptomatic infection using quantitative PCR.
2. To study the role of host factors (age, and bacterial and viral co-infection) on infection by M. pneumoniae.
3. To investigate the relationship between M. pneumoniae genotype and virulence.

### Study design

Methods: In healthy children and children visiting the emergency department because of an RTI, clinical data, nasal and pharyngeal swab and nasal washing will be collected. Bacterial and viral causes of respiratory tract infections will be analyzed.
RTI by M. pneumoniae will be defined by RTI symptoms in combination with serology and/or culture positive for M. pneumoniae.

### Study burden and risks

not applicable

## Contacts

### Public

Erasmus MC, Universitair Medisch Centrum Rotterdam

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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

Group A
· Age: ³3 months and <= 16 years
· Clinical signs and symptoms of community-acquired upper or lower respiratory tract infection (i.e. cough, rhinitis, sore throat, wheezing and fever).
· Written informed consent;Group B (control group)
· Age: ³3 months and <= 16 years
· Written informed consent
· Healthy controls: absence for ³1 week of clinical signs and symptoms of community-acquired upper or lower respiratory tract infection (i.e. cough, rhinitis, sore throat, wheezing and fever)

## Exclusion criteria

Severe concomitant disease (chronic lung disease, neoplasia, liver or kidney disease,

immunodeficiency, cardiovascular disease, psychomotor impairment). Nosocomial infection. Use of antibiotics in the 48 hours that preceded enrollment or azithromycin within 1 week before enrollment

# Study design

## Design

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| Study type: | Observational invasive |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Diagnostic |

## Recruitment

NL

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| Recruitment status: | Recruiting |
| Start date (anticipated): | 25-06-2008 |
| Enrollment: | 1000 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 06-05-2008 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 10-07-2009 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO | |

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| Date: | 22-09-2009 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 01-07-2010 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 07-12-2010 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

# 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 | NL20418.078.08 |