Comparison, optimization en evaluation of new and fast molecular diagnostic techniques for detection of atypical bacterial respiratory tract pathogens in clinical samples from patients with CAP.

Published: 10-01-2008
Last updated: 11-05-2024

The objective of this study is to compare, evaluate and validate some commercial molecular diagnostic techniques for atypical respiratory tract infections. Simultaneously, we intend to define the most relevant clinical material per etiological agens...

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

Summary

ID

NL-OMON32296

Source
ToetsingOnline

Brief title
ARTI-study

Condition

- Bacterial infectious disorders
- Respiratory tract infections

Synonym
Atypical pneumonia, 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: Atypical respiratory tract infection, Chlamydophila, Legionella, Molecular Microbiological diagnostiscs, Mycoplasma

Outcome measures

Primary outcome

The main study parameters are the results obtained with the different molecular

diagnostic methods.

Secondary outcome

The secondary study parameter will be the results obtained for the different

clinical materials.

Study description

Background summary

Bacterial community-acquired pneumonia (CAP) is one of the most common infectious diseases. CAP can be distinguished in 2 types: typical pneumonia, caused by e.g. Streptococcus pneumoniae or Haemophilus influenzae and atypical pneumonia caused by Mycoplasma pneumoniae, Legionella pneumophila or Chlamydophila pneumoniae. Currently, therapeutic protocols include treatment for atypical pneumonia only when there is a high clinical suspicion or after exacerbation of the infection. Clinically, it is not always possible to distinguish atypical pneumonia from atypical pneumonia. Thus, it can be that patients receive suboptimal therapy.
Isolation by culture of atypical pathogens is laborious or impossible, e.g. caused by transport problems and rapidly decreasing viability. For most diagnostic laboratories it is a major challenge to diagnose these bacterial pathogens. Current infection with M. pneumoniae, C. pneumoniae or L. pneumophila is based on a four-fold or greater rise in antibody titer between paired acute and convalescent-phase sera within 2 weeks.
However, a second serum specimen is necessary for reason of determining

infection status, and will delay the diagnosis with two extra weeks. Molecular techniques may be helpful in rapid and robust diagnosis of atypical pneumonia. Especially since real time PCR assays and (semi) automated DNA isolation from clinical specimens has become available.

Study objective

The objective of this study is to compare, evaluate and validate some commercial molecular diagnostic techniques for atypical respiratory tract infections.
Simultaneously, we intend to define the most relevant clinical material per etiological agens. For this purpose, next to the standard diagnostic procedure, an extra throatswab, a nasopharyngeal aspirate and a urine sample will be collected. The results of the conventional diagnostics (serology) and an in-house molecular-based target amplification technique will be compared with the results of the new diagnostic tests, obtained from different clinical samples.

Study design

This study follows a prospective design. Routine diagnostic assays will include assays for detection by culture, PCR or serology of infection with respiratory viruses, bacteria causing typical pneumonia, and, when indicated, special techniques required for specific detection of parasites, fungi or mycobacteria.
In addition to this routine standard diagnostic workup, a range of assays will be included to detect infection with pathogens causing atypical pneumonia:
· Strand Displacement Amplification (SDA, BDProbeTec, Beckton & Dickinson)
· Multi Ligase Probe-mediated Amplification (MLPA, Pathofinder)
· Nucleic Acid Sequence Based (NASBA, NucliSens EasyQ, bioMérieux)
· In house PCR, MCRZ
· Virological PCR panel.

As a reference, serological diagnosis using enzyme immunoassays will be chosen. Comparison with the current state of the art methodology will be possible.

Study burden and risks

Patients suspected for CAP will be asked to participate. Patients will be informed by the medical practitioner and asked for informed consent.For minors under 18, the parent(s) or guardian(s) will be asked for informed consent. Minors between 12 and 18 also need to sign themselves.
The risks considered with participation can be considered negligible and the burden for obtaining a throat swab, a nasopharyngeal aspirate and a urine sample can be considered minimal.
Because all people, including minors, can get CAP, it is necessary to include

all patients.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
3015 CE Rotterdam
Nederland
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
3015 CE Rotterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

All patients with symptoms of CAP.

Exclusion criteria

Patients will be excluded from the study if they disagree with the conditions as mentioned in the informed consent or if investigator believes that subject is not suitable for inclusion in the study (i.e. not compliant with subject requirements).

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):	11-02-2008
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO

Date:	10-01-2008
Application type:	First submission
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	NL19970.078.07