Microbiological evaluation of BAL fluid from patients with nosocomial Pulmonary Aspiration Syndrome compared to BAL fluid from hospitalized patients undergoing inspection bronchoscopy. A pilot study.

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Validation of microbiological analyses of BAL (broncho alveolar lavage) fluid in patients suspected of nosocomial bacterial aspiration pneumonia.

Ethical review	Approved WMO
Status	Pending
Health condition type	Respiratory tract infections
Study type	Observational invasive

Summary

ID

NL-OMON35468

Source
ToetsingOnline

Brief title
PAS pilot

Condition

- Respiratory tract infections

Synonym
aspirationpneumonia, pulmonary aspiration syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar
Source(s) of monetary or material Support: pulmoscience alkmaar

Intervention

Keyword: Aspiration, BAL, Micobiology, pathogens

Outcome measures

Primary outcome

Evaluation of microbiological pathogens isolated from BAL fluid in order to validate this technique for further research. BAL fluid obtained from patients suspected for bacterial pulmonary infection must show growth of pathogens of at least 103 colony forming units (CFU)/ml. Furthermore in comparison to the controls a difference of at least 104 CFU/ml must be shown in order to identify the organism as a pathogen. Reason for this is the fact it otherwise should be identified as a colonist[5, 6]. After validation of microbiological findings of BAL fluid in both groups, we will start the definite trial comparing the outcome of BAL specimens in patients with PAS. Furthermore, we look at biochemical markers in BAL and serum such as C-reactive protein, pro-calcitonine and amylase.

Secondary outcome

niet van toepassing

Study description

Background summary

Pulmonary Aspiration Syndrome (PAS) can be divided in two main entities:

firstly chemical pneumonitis due to acid inoculum aspiration and secondly bacterial aspiration pneumonia[1-3]. Less is known about the microbiological and biochemical aspects of PAS. PAS has a high prevalence and incidence, but is frequently under diagnosed. Also it is an important cause of serious illness and death among hospitalized patients[4]. It will be favorable to diagnose and distinguish both entities properly in order to give adequate treatment or prevent overtreatment. No antibiotics are required for aspiration (chemical) pneumonitis while specific antibiotics are needed for aspiration pneumonia. If we are able to identify specific pathogens (e.g. anaerobic bacteria) from patients highly suspected for bacterial aspiration pneumonia compared to patients who have not aspirated we can start further research after pathogens and biochemical markers in patients with PAS.

Study objective

Validation of microbiological analyses of BAL (broncho alveolar lavage) fluid in patients suspected of nosocomial bacterial aspiration pneumonia.

Study design

Study design: Pilot study. Comparison between patients with PAS and a group of in hospital patient*s indicated for inspection bronchoscopy.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The risk of participating this pilot study is low. Laboratory, radiographic examinations and bronchoscopy are commonly used as diagnostic procedures in both study groups. Performing BAL is an additional procedure leading to temporarily increase in shortness of breath and coughing. A decline in oxygen saturation will be treated by supplemental oxygen. In case O2 saturation drops below 90% with supplemental oxygen the bronchoscope procedure will be terminated. An oropharyngeal swab will be collected from each patient. This does not have any related burden nor risk for the patient.

Contacts

Public
Medisch Centrum Alkmaar

wilhelminalaan 12
1815 JD alkmaar
NL
Scientific

Medisch Centrum Alkmaar

wilhelminalaan 12
1815 JD alkmaar
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Patiënt aged 18 and older
• The presence of comorbidity with high risk for aspiration.
• Increase in respiratory symptoms such as shortness of breath, cough with or without expectoration of sputum, presence of fever for < 24 hours with fever defined as >38.5 *C.
• Elevated or increased CRP >50 mmol/l and leukocyte count > 10.0 109/l
• New consolidation X- thorax or CT-thorax after clinical suspicion of intrapulmonary infection and/or inflammation.
• Informed consent

Exclusion criteria

- Lowered conciousness: desoriented in time, place, person.
- Obstruction pneumonia (e.g. from lung cancer).
- Severe immunosuppression (HIV infection, chemotherapy).
- Suspicion of TBC.
- Mechanical ventilation <72 h prior to inclusion
- Respiratory insufficiency defined as peripheral O2 saturation under 90% without supplemental oxygen and/or breathing frequency > 22/minute
- Treatment with antibiotics less then 48 hours prior to inclusion
- history or anamnesis for aspiration in controll group patients

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	16-03-2010
Enrollment:	24
Type:	Anticipated

Ethics review

Approved WMO Date:	30-03-2010
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	NL28237.094.09