Childhood study on respiratory pathogens from induced sputum

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To determine the effectiveness of sputum induction in retrieving good quality sputum, identifying bacterial and viral pathogens in lower respiratory tract infections and determine the practical applicability of sputum induction in general pediatric...

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

Summary

ID

NL-OMON35654

Source
ToetsingOnline

Brief title
Induced sputum

Condition

- Respiratory tract infections

Synonym
'lower respiratory tract infections', 'lung infection'

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: Het betreft hier een niet-gesponsord onderzoek. Financiering zal geschieden uit het eigen budget van de deelnemende afdelingen en van de beschikbare onderzoeksgelden voor arts-assistenten werkzaam in het JBZ.

Intervention

Keyword: Children, Induced sputum, Microbiology, Respiratory tract infections

Outcome measures

Primary outcome

The quality of induced sputum, defined as <25 squamous cells and >25 leukocytes

per visual field under light microscopy.

Secondary outcome

To identify bacterial and viral pathogens of lower respiratory tract infections.

To determine the practical applicability of sputum induction in general

pediatric practice.

To determine the prevalence of Coxiella burnetii infections (Q fever) in

children with lower respiratory tract infections.

To determine the prevalence of Influenza A type H1N1-infections in children

with lower respiratory tract infections.

Study description

Background summary

Lower respiratory tract infections are a major disease burden in children and give an annual death rate of 2 million world wide. In most cases, the pathogens are not identified, current dia

(Current diagnostic tests provide little differentiation between bacterial and viral pathogens, and in most cases the pathogens are not identified.)

Adults can produce sputum that can be analysed for pathogens, but in children this is often not possible because they cannot produce sputum. By inhaling hypertonic saline solution, sputum production increases and a coughing reflex is prompted. This study investigates the effectiveness of sputum induction in retrieving good quality sputum in children with suspected lower respiratory tract infections.

Study objective

To determine the effectiveness of sputum induction in retrieving good quality sputum, identifying bacterial and viral pathogens in lower respiratory tract infections and determine the practical applicability of sputum induction in general pediatric practice.

Study design

A prospective cohort study.

Study burden and risks

Sputum induction is a non-painfull procedure but can be experienced as discomforting. Complications are rare and consist of epistaxis, vomiting, transient wheezing and mild, reversible hypoxia (oxygen saturation 88-92%). During the routinely performed venipuncture, extra blood is collected. If no blood was collected during routine investigations, a venipuncture will be performed. Urine is also collected, if necessary by collection bag. After 4 weeks, another venipuncture is performed for convalescent serology testing. If the above mentioned procedures can identify the pathogens, current overtreatment with antibiotics can be decreased and hospital admissions can be shortened or even prevented. If bacterial pathogens are determined during the intervention, the current antibiotic treatment of the study subject can be altered, which is of direct benefit to the study subject.

Contacts

Public
Jeroen Bosch Ziekenhuis

Tolbrugstraat 11
5211 RW
NL
Scientific
Jeroen Bosch Ziekenhuis

Tolbrugstraat 11
5211 RW
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Tachypnea combined with at least one of: elevated body temperature, cough, dyspnea or abdominal pain

Exclusion criteria

- Acute exacerbation of asthma in the last 4 weeks. This is defined as requiring systemic coricosteroids, hospital admission and/or use of ß-sympaticomimetics >400 µg per day
- Oxygen saturation < 92% without oxygen therapy or severely ill impression
- Anatomical abnormalities of the respiratory tract presenting with inspiratory stridor
- Use of β-blockers, diuretics or theophylline

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-10-2009
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	25-09-2009
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	09-06-2010
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	22-12-2010
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL28965.028.09