Point-of-Care C-reactive protein to assist in primary care management of children with lower respiratory tract infection

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Analyse costs and effects of point of care (POC) C-reactive protein (CRP) measurement in children with non-severe lower respiratory tract infection (LRTI) in primary care.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON41688

Source
ToetsingOnline

Brief title
PRICE

Condition

- Bacterial infectious disorders
- Respiratory tract infections

Synonym
acute bronchitus, cough, Lower Respiratory Tract Infections (LRTI)

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: ZonMw,Axis-Shield,Saltro diagnostisch centrum,Star Medisch Diagnostisch Centrum

Intervention

Keyword: acute bronchitis, antibiotics, point of care, primary care

Outcome measures

Primary outcome

The primary outcome is the % antibiotic prescriptions during 28 days after

first consultation.

Secondary outcome

Secondary outcomes include health care use, costs, adverse events, quality of

life (QOL), symptoms, and cost-effectiveness.

Study description

Background summary

Title of the study: Point-of-Care C-reactive protein to assist in primary care management of children with lower respiratory tract infection

In children, lower respiratory tract infection (LRTI) is among the most frequent reasons for consulting a general practitioner (GP). LRTI includes pneumonia, which is a rare but severe infection, and acute bronchitis which is merely self-limiting. Despite the fact that antibiotics are only recommended in suspected pneumonia, the majority of children with LRTI in general practice are still prescribed antibiotics.

We hypothesize that using POC CRP will help to reduce the proportion (%) of children with non-severe LRTI treated with antibiotics without increasing complications, and is cost effective compared to care as usual.

Study objective

Analyse costs and effects of point of care (POC) C-reactive protein (CRP) measurement in children with non-severe lower respiratory tract infection (LRTI) in primary care.

Study design

A cluster randomised controlled two arm trial with 28 days follow up.

Intervention

GP practices are randomised to usual care, or usual care plus POC CRP. 22 practices from three different regions in the Netherlands will be involved (Utrecht, Rotterdam and Maastricht). Children can also be included at an out-of-hours service, These patients will be randomised individually. In total 354 patients will be included (177 in each arm).

Study burden and risks

We hypothesize that POC CRP will reduce the proportion (%) of children with non-severe LRTI treated with antibiotics without increasing complications. Therefore we expect the number of events to be comparable within both study arms and without an increased risk for the patients because of participation in the study. The risk related to the blood drawn from a finger prick, the only invasive test related to the study, is negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Children aged between 3 months and 12 years presenting to the GP with a non-severe LRTI.
- LRTI will be defined as acute cough (shorter than 21 days) with (reported) fever (>38 °C).
- The parent of the patient should be able to provide written informed consent and be willing to (help to) complete the patient diary.

Exclusion criteria

- immunodeficiency
- recent (previous four weeks) use of systemic antibiotics and/or corticosteroids
- being severely ill as judged by the GP based on symptoms and signs
- highly suspected of having pneumonia;Being severely ill or highly suspected of pneumonia includes: signs of dehydration, cyanosis, tachypnoe, lower level of consciousness or fever during > 5 days, no food or fluid intake, or otherwise judged as being severely ill by the GP.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-01-2014
Enrollment:	354
Type:	Actual

Medical products/devices used

Generic name:	Point-of-Care CRP measurement using the Afinion device of Axis-Shield
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	24-12-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	21-01-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	26-03-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	06-08-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	27-08-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	21-10-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	05-12-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	

Date:	30-12-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	05-02-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	04-03-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	23-06-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	28-12-2015
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

ID: 22451
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL45601.041.13
OMON	NL-OMON22451