PRICE onderzoek: Het gebruik van een CRP test in de huisartsenpraktijk bij de behandeling van kinderen met een lage luchtweginfectie

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22451

Source
Nationaal Trial Register

Brief title
PRICE

Health condition

Children with non severe lower respiratory tract infections

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: ZonMW, Saltro diagnostisch centrum. Star medisch diagnostisch centrum. Axis Shield

Intervention

Outcome measures

Primary outcome

Antibiotic reduction expressed in the percentage of children prescribed antibiotics in the first 28 days after consultation, as compared to a strategy without POC CRP measurement (usual care)

Secondary outcome

-Health care use
-Costs
-Adverse events
-Quality of life (QOL)
-Functional Health status
-Symptoms
-Cost-effectiveness

Study description

Background summary

Rationale: LRTI is one of the most common reasons to consult a general practitioner (GP) in children. Despite the fact that antibiotics are only recommended in suspected pneumonia, the majority of children presenting with acute bronchitis are prescribed antibiotics. point of care (POC) C-reactive protein (CRP) measurement has shown to reduce antibiotic prescribing for lower respiratory tract infection in adults without compromising patients' recovery and satisfaction with care. In children however, no evidence is yet available.
Objective: To analyse costs and effects of POC CRP measurement in children with non-severe lower respiratory tract infection (LRTI) in primary care.
Study design: Cluster randomised controlled two arm trial with 28 days follow up. GP practices are randomised to usual care, or usual care plus POC CRP. Twenty-two practices from Utrecht, Rotterdam and Maastricht areas will be involved, a total of 356 children will particpate.
Study population: Children between 3 months and 12 years presenting with non-severe LRTI.
Study endpoints: Primary outcome is antibiotic reduction expressed in the % of children prescribed antibiotics in the first 28 days after consultation, as compared to a strategy without POC CRP measurement (usual care). Secondary outcomes include health care use, costs, adverse events, functional health status, symptoms and cost-effectiveness.

Study objective

Point of care measurement of C-reactive protein in children with non severe lower respiratory tract infection in primary care will reduce the proportion of children treated with antibiotics without increasing complications, and is cost effective compared to care as usual

Study design

primary outcome after 28 days
secondary outcome after 3 months

Intervention

GP practices are randomised to usual care, or usual care plus point of care CRP. All parents are asked to fill out a 28-day online diary about the child's symptoms, health care use and costs

Contacts

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Eligibility criteria

Inclusion criteria

-Children aged between 3 months and 12 years
-Presenting to the GP with a non-severe LRTI: acute cough (shorter than 21 days) with (reported) fever (>38 °C, shorter than 5 days)
-Parents of the patient should be able to provide written informed consent and be willing to complete the patient diary.

Exclusion criteria

-Immunodeficiency
-Underlying severe pulmonary disease like Cystic Fibrosis, Bronchopulmonary Dysplasia,

congenital pulmonary defects
-Serious congenital defects, such as Down syndrome, congenital heart defects, neuromuscular disease, severe developmental retardation
-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
-referral to specialist or emergency department deemed necessary by GP

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-01-2014
Enrollment:	354
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-01-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41688
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4263
NTR-old	NTR4399
CCMO	NL45601.041.13
OMON	NL-OMON41688

Study results