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

Gepubliceerd: 14-01-2014 Laatst bijgewerkt: 15-05-2024

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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22451

Bron
Nationaal Trial Register

Verkorte titel
PRICE

Aandoening

Children with non severe lower respiratory tract infections

Ondersteuning

Primaire sponsor: University Medical Center Utrecht
Overige ondersteuning: ZonMW, Saltro diagnostisch centrum. Star medisch diagnostisch centrum. Axis Shield

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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)

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

primary outcome after 28 days
secondary outcome after 3 months

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

-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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	15-01-2014
Aantal proefpersonen:	354
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-01-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41688
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten