STRAP – STudy to Reduce Antibiotic prescription in childhood Pneumonia

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The aim of this study is to reduce antibiotic prescriptions by use of a clinical decision rule in febrile children suspected for CAP with unchanged outcome. Specific research questions are: 1. Does a decision rule reduce the use of antibiotics in…

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28856

Bron
NTR

Verkorte titel
STRAP

Aandoening

children; pneumonia; prediction; antibiotic use; antibiotica; pneumonie; kinderen

Ondersteuning

Primaire sponsor: Erasmus MC - Sophia
Overige ondersteuning: Dutch national health council (ZonMW)
Innovatiefonds zorgverzekeraars

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Number of (narrow-spectrum) antibiotic prescriptions and its percentage within the total

included population (benefit); Strategy failures (children with complications of CAP within 7 days) (safety).

Toelichting onderzoek

Achtergrond van het onderzoek

Unnecessary prescription of antibiotics highly contributes to the development of antibiotic resistance, a world wide threat to
health. We are in need to improve the recognition of children that benefit from antibiotic treatment for comunity-acquired
pneumonia (CAP).

Aim:

To safely reduce antibiotic prescription by a clinical decision rule (Feverkidstool) in febrile children suspected of CAP.

Design:

Stepped wedge trial with implementation of the Feverkidstool guiding antibiotic treatment in children suspected of CAP in 7
hospitals.
Population:
Febrile children (1 month – 5 years) at the emergency care department with signs of CAP in 7 Dutch hospitals.

Outcomes:

Primary: Number of antibiotic prescriptions (benefit); strategy failures within 7 days (safety).
Secondary: Compliance to the rule;
Percentage of narrow spectrum antibiotics; Duration/doses of antibiotics; Complications of CAP; Costs of outcome measures.

Intervention:

Clinical decision rule (Feverkidstool) for the individual risk for CAP and other SBI guiding a targeted approach for antibiotic
prescription.
Analysis:
A generalized linear mixed model with antibiotic prescription as dependent will be used to correct for clustering in centers and
time-effects. Time-effects will be included as fixed effect. Covariates includes the predicted risk for CAP (low, intermediate and

high), patient age, triage urgency and season.
Power analysis:
A sample size of 1100 children with a suspicion of CAP in 24 months will be sensitive to detect an absolute reduction of 10%
(low risk) to 15% (intermediate risk) of antibiotic prescription with a power of 0.9 and an alpha of 0.05.
Schedule:
M0-3: preparation; M4-15 datacollection preimplementation; M13-15 implementation; M16-M27 datacollection
postimplementation; M28-30 Datanalysis, reporting.
Impact:
The Feverkidstool improves application of current insights on reduced antibiotic presicription in children suspected of CAP in
routine care.

Changes/Added information
dd 21-12-2016:
to provide sufficient inclusions we introduce an eighth hospital, Lange land hospital Zoetermeer

dd 20-8-2018
Interim analysis of inclusions during the first year showed a higher antibiotic prescription than previously assumed: in low risk children we observed 35-45% antibiotic prescription; in the intermediate group this is 40%. Therefore we assume a reduction of 15% in both the low and intermediate risk group. Remodelling with these numbers and similar assumptions as above shows that an effect of 15-20% antibiotic reduction can be assessed in a sample of 800-900 children.

Doel van het onderzoek

The aim of this study is to reduce antibiotic prescriptions by use of a clinical decision rule in febrile children suspected for CAP with unchanged outcome. Specific research questions are:

1. Does a decision rule reduce the use of antibiotics in children with suspected CAP?

2. Does the use of a decision rule do not harm those whose treatment is modified as a result?

3. What is the compliance to a decision rule guiding clinicians on treatment for childhood CAP?

4. What is the cost benefit of the implementation of the feverkidstool in the diagnostic evaluation of a child suspected of CAP?

Onderzoeksopzet

Month 1-3: Preparation study and preparation baseline data collection of eligible patients

Month 4-15: Preimplementation phase datacollection, development webbased dataregistry and feverkidstool. Evaluation possibilities to integrate the feverkidstool within the local ICT-environment
Month 13-15: Training ED personnel (nurses, paediatricians (in training)) in feverkidstool
Month 16-27: Postimplementation phase data collection of eligible patients (clinical characteristics, diagnoses and antibiotic therapy).

Month 28-30: Evaluation, datanalysis and interpretation; Writing report

Onderzoeksproduct en/of interventie

-Feverkidstool: a clinical decision rule that assess the individual risk for pneumonia in children with fever

-a risk based strategy for treatment advice (discharge, watchfull waiting, or antibiotics) will be applied

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

children aged 1 month – 5 years with fever (parent reported and/or measured during physical examination T >38°C) with signs suspected of community acquired pneumonia (CAP)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-febrile children with antibiotic treatment during the week prior to the ED visit

-children with comorbidity, i.e. hemodynamic relevant cardiac disease, pulmonary, neurologic disease or (primary of secondary) immunodeficiency

-children with an obvious single other infectious focus (cutaneous, otitis media, rhinitis), those with signs of complicated pneumonia at the moment of presentation (i.e. respiratory failure, pleura empyema, pneumothorax, suspicion of septicaemia), those with (self-reported) intolerance of amoxicillin, and those with suspicion of resistant pathogens due to a visit to foreign countries 2 months prior to the ED visit

-patients not understanding or not able to act on safety-net instructions (due to language problems or logistics) in case of deterioration

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-10-2015
Aantal proefpersonen:	1100
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
Data will be stored in DANS, and will contain processed data, datadocumentation and syntaxes. Biobank samples are stored at the department MMIZ of ERasmusMC

Ethische beoordeling

Positief advies

Datum:	23-07-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5178
NTR-old	NTR5326
Ander register	NL47593.078.14 : ZonMW 836041001

Resultaten