STRAP – STudy to Reduce Antibiotic prescription in childhood Pneumonia

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28856

Source
NTR

Brief title
STRAP

Health condition

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

Sponsors and support

Primary sponsor: Erasmus MC - Sophia
Source(s) of monetary or material Support: Dutch national health council (ZonMW) Innovatiefonds zorgverzekeraars

Intervention

Outcome measures

Primary outcome

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).

Secondary outcome

-Compliance to the advice of the feverkidstool; percentage and number of narrow versus broad-spectrum antibiotic prescriptions; Duration and dosages of antibiotic prescriptions

-Safety: Number of complications of pneumonia, association of isolated pathogens with complicated CAP course

Study description

Background summary

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.

Study objective

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?

Study design

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

Intervention

-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

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Eligibility criteria

Inclusion criteria

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)

Exclusion criteria

-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

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial

Control: Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2015
Enrollment:	1100
Type:	Actual

IPD sharing statement

Plan to share IPD: Yes

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

Ethics review

Positive opinion

Date:	23-07-2015
Application type:	First submission

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
NTR-new	NL5178
NTR-old	NTR5326
Other	NL47593.078.14 : ZonMW 836041001

Study results