Study to Reduce Antibiotic prescription in childhood Pneumonia: implementation of a validated decision rule

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to safely reduce antibiotic prescription by a clinical decision rule in febrile children suspected of CAP

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bacterial infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON47230

Source
ToetsingOnline

Brief title
Study to Reduce Antibiotic prescription in childhood Pneumonia

Condition

- Bacterial infectious disorders

Synonym
lower respiratory tract infections, pneumonia

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: antibiotics, decision support, fever, pediatric

Outcome measures

Primary outcome

Rate of narrowspectrum antibiotic prescriptions and uneventful recoveries after

CAP

Secondary outcome

Compliance to the rule; Safetyendpoints

Study description

Background summary

Community acquired pneumonia (CAP) is the largest cause of death in children and among the most frequent diagnoses in febrile children. The majority of young children suspected of CAP suffers from self-limiting or viral causes, that don't need treatment. We are in need to improve the recognition of children that benefit from antibiotic treatment for CAP.

Study objective

to safely reduce antibiotic prescription by a clinical decision rule in febrile children suspected of CAP

Study design

Stepped wedge design with sequential implementation of a clinical decision rule guiding antibiotic treatment in children suspected of CAP

Intervention

Clinical decision rule for the individual risk for CAP and for other SBI guiding a targeted approach for antibiotic prescription

Study burden and risks

For the individual patient antibiotic use has risks of side-effects (nausea, diarrhea, allergic reactions). At population level it is associated with antibiotic resistance worldwide. The proposal implies pragmatic scientific research applied in routine care with direct benefit for the patient. From the safety side, the study risks are considered to be acceptable for the patient. The strategy for initiating antibiotic treatment and on duration of therapy in this project is based on current guidelines and a well validated decision rule, and does not involve experimental approaches. Next, the study includes a well-defined follow-up scheme to detect potential complications. The burden to participate in this study concerns the very low risk of safety-endpoints (severe complications of CAP), nose specimens for microbiological testing and one extra control visit, that may be performed by telephone in the majority.The studyhas been discussed with the foundation Kind & ZIekenhuis (K&Z). The principles of K&Z are optimizing the balance between the number of diagnostic and therapeutic procedures and the child*s quality of life; these fit to the present study. They recognize the relevance of the study.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 80
Rotterdam 3015CN
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 80
Rotterdam 3015CN
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

children aged 1 month - 5 years (60 months) with fever and signs suspected of pneumonia

Exclusion criteria

1) comorbidity resulting in higher risk of (complications of) infectious diseases, i.e. cardiac, pulmonary, renal, neurologic disease or immunodeficiency
2)children with obvious single infectious focus (cutaneous, otitis media, rhinitis)
3) children with parents not able to understand or to act on safety-net instructions

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2016
Enrollment:	900
Type:	Actual

Ethics review

Approved WMO
Date: 04-03-2015

Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-04-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-06-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-09-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-02-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-10-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL47593.078.14