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Usefulness of a novel biomarker procalcitonin to guide antibiotic therapy in children with chest infections

Submission date	Recruitment status	[_] Prospectively registered
03/01/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/03/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/12/2020	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of procalcitonin guidance on antibiotic use, quality of care, hospitalisation, and time to recovery in children with lower respiratory tract infections

Acronym
ProPAED

Study objectives
Respiratory tract infections are the leading cause of medical consultations and antibiotic (AB) prescriptions in childhood. Improving the diagnostic accuracy, facilitating early detection of LRTIs in need of AB therapy, reducing AB misuse and decreasing unnecessary utilisation of hospital resources for lower respiratory tract infections (LRTI) will improve patient care and may have a major impact on reducing AB resistance and heath care costs.

Hypothesis:
Compared to management according to internationally recognised guidelines, procalcitonin (PCT) guidance will lead to reduced AB use overall, earlier detection of LRTI in need of AB treatment and decreased hospitalisation rate, with a similar clinical outcome and time to recovery measured by days of restriction due to the LRTI.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Basel, approved in January 2009 (ref: EKBB 369/08)

Study design
Open randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Diagnostic

Participant information sheet
Patient information sheet can be found at: http://propaed.pidb.ch/propaed/

Health condition(s) or problem(s) studied
Paediatric lower respiratory tract infections

Interventions

Stratified by centre and type of LRTI, patients will be randomised to management according to internationally recognised guidelines ("guideline group") versus PCT-guided AB therapy ("PCT group"). In the control group, the use of internationally recognised guidelines for the management of LRTIs will be strictly adhered to. In the PCT group, initiation or continuation of AB will be increasingly discouraged (<0.25 or <0.1 ug/L) or increasingly encouraged (>0.25 or >0.5 ug/L) based on the PCT level. In AB-treated outpatients or discharged patients, the duration of AB will be based on the most recent PCT level. A re-evaluation after 6 to 24 hours is recommended if AB are withheld.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Antibiotic prescription rate at Day 1, 3, 5 and 14.

Secondary outcome measures
1. Time to recovery (days with restriction from LRTI)
2. Rate and duration of hospitalisation
3. Complication rate
4. Measures of laboratory and clinical outcome
5. Side effects from AB
6. Disease activity scores

Endpoints will be assessed at day 1, 3 and 5 in the form of a medical consultation at the hospital, and after 14 days by structured phone interviews conducted by blinded investigators.

Overall study start date
10/01/2009

Completion date
09/01/2010

Eligibility

Key inclusion criteria
1. Both males and females, 1 month to 18 years of age
2. Two pre-specified sub-groups will be recruited:
2.1. Patients with acute LRTI based on clinical diagnosis
2.2. Patients with X-ray confirmed community acquired pneumonia (CAP)

Participant type(s)
Patient

Age group
Child

Lower age limit

1 Months

Upper age limit
18 Years

Sex
Both

Target number of participants
338

Total final enrolment
337

Key exclusion criteria
1. Patients who have been hospitalised within the previous 14 days
2. Patients with immune-suppression, chronic infection, or a terminal condition
3. Patients lacking informed consent
4. Insufficient knowledge of German (in a family member)

Date of first enrolment
10/01/2009

Date of final enrolment
09/01/2010

Locations

Countries of recruitment
Switzerland

Study participating centre
University Children's Hospital Basel
Basel
Switzerland
4005

Sponsor information

Organisation
University Children's Hospital Basel (Switzerland)

Sponsor details
Postfach
Basel

Switzerland
4005

Sponsor type
Hospital/treatment centre

Website
http://www.ukbb.ch/

ROR
https://ror.org/02nhqek82

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Children's Hospital Basel (Switzerland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	06/08/2013	30/12/2020	Yes	No