

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

Submission date
03/01/2009

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
25/03/2009

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
30/12/2020

Condition category
Infections and Infestations

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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 health 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