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Procalcitonin-guided antibiotic use in Acute Respiratory Tract Infections (ARTIs) in primary care

Submission date
18/01/2005

Recruitment status
No longer recruiting

Registration date
15/02/2005

Overall study status
Completed

Last Edited
20/09/2017

Condition category
Respiratory

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00099840

Protocol serial number
EKBB 254/04

Study information

Scientific Title
Procalcitonin-guided antibiotic use in Acute Respiratory Tract Infections (ARTIs) in primary care

Acronym
PARTI-Study

Study objectives
Acute respiratory tract infections (ARTI) are among the most frequent reasons for seeking medical attention in primary care. Although from predominantly viral origin, ARTIs are the most important condition for the prescription of antibiotics (AB), mainly due to the difficulty in primary care to differentiate between viral and bacterial etiology. Unnecessary AB use increases drug expenditures, side effects and AB resistance. A novel approach is to guide AB use by procalcitonin (ProCT), since serum levels are elevated in bacterial infections but remain lower in viral infections and inflammatory diseases. We aim to compare a strategy based on evidence-based guidelines with ProCT guided AB therapy in ARTIs with respect to outcome (days with restriction) and AB use.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute respiratory tract infections

Interventions
All participating physicians will receive evidence-based guidelines for the management of patients with ARTIs. Patients with ARTI and in need of antibiotics by physicians' clinical judgment and with informed consent will be randomized to procalcitonin (ProCT) guided antibiotic prescription ("ProCT group") versus guidelines guided antibiotic prescription ("control group").

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Days with restrictions from ARTI

Key secondary outcome(s)
1. Rate of AB prescriptions; days with AB use
2. Symptoms from ARTI
3. Relapse rate from ARTI within 28 days
4. Days with side effects from ABs and off work
5. Cost-effectiveness

Completion date
31/03/2006

Eligibility

Key inclusion criteria
18 years or older, with ARTI of >1 and <28 days duration and in need of antibiotics based on the clinical judgment of the primary care physician

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Patients without informed consent
2. Not fluent in German
3. Antibiotic pretreatment in previous 28 days
4. Severe immune-suppression

Date of first enrolment
01/12/2004

Date of final enrolment
31/03/2006

Locations

Countries of recruitment
Switzerland

Study participating centre
University Hospital Basel
Basel
Switzerland
4031

Sponsor information

Organisation
University Hospital Basel (Switzerland)

ROR
https://ror.org/04k51q396

Funder(s)

Funder type
University/education

Funder Name
University Hospital Basel - Clinic of Endocrinology, Basel Institute of Clinical Epidemiology (BICE), Dept. of Internal Medicine, Dept. of Central Laboratories (infrastructure)

Funder Name
BRAHMS AG, Hennigsdorf, Germany (assay material)

Funder Name
Schweizerischer Nationalfonds zur Förderung der Wissenschaftlichen Forschung

Alternative Name(s)
Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, The Swiss National Science Foundation (SNSF), SNF, SNSF, FNS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	13/10/2008		Yes	No
Protocol article	protocol	18/08/2005		Yes	No
Other publications	secondary analysis	24/03/2016		Yes	No