

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

Submission date 18/01/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 15/02/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 20/09/2017	Condition category Respiratory	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00099840

Secondary identifying numbers

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

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

Days with restrictions from ARTI

Secondary outcome measures

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

Overall study start date

01/12/2004

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

400

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)

Sponsor details

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Sponsor type

University/education

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, SNF, SNSF, FNS

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

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?
Protocol article	protocol	18/08/2005		Yes	No

Results article	results	13/10/2008	Yes	No
Other publications	secondary analysis	24/03/2016	Yes	No