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Registry of procalcitonin-guided antibiotic therapy in patients with lower respiratory tract infections outside of study conditions: Pro-REAL - a real-life" survey

Submission date
18/09/2009

Recruitment status
No longer recruiting

Registration date
16/10/2009

Overall study status
Completed

Last Edited
17/07/2012

Condition category
Infections and Infestations

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.proreal.li/

Contact information

Type(s)
Scientific

Contact name
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Contact details
Tellstrasse
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Aarau
Switzerland
5001

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
ProREAL

Study objectives
Duration of antibiotic therapy for patients with lower respiratory tract infections can be shortened by application of a procalcitonin-based algorithm in real-life conditions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Switzerland:
1. Ethics Committee of Aargau (Kantonale Ethikkommission Kanton Aargau) (EKAG), approved on 06/10/2008 (ref: 2006/48)
2. Ethics Committee of Basel (Ethikkommission Beider Basel) (EKBB), approved on 29/07/2008 (ref: 236/08)

Ethics approvals for trial centres in France: Pending as of 18/09/2009

Study design
Observational prospective longitudinal study

Primary study design
Observational

Secondary study design
Multi-centre

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Patient information (in English, French and German) can be found at: http://www.proreal.li/

Health condition(s) or problem(s) studied
Respiratory tract infections

Interventions

The participants will be contacted approximately 30 days after the start of the treatment to conduct a telephone interview lasting approximately 10 minutes. They will be asked about any persisting complaints, possible side-effects of the antibiotics (such as diarrhoea and nausea) and recurrence of the respiratory tract infection with or without antibiotic treatment. They will also be asked whether they had to visit the GP or the hospital, and if so, how many times.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Duration of antibiotic treatment

All primary and secondary outcome measures will be assessed by a telephone interview 30 days after the start of the treatment.

Secondary outcome measures
1. Adherence to procalcitonin algorithm
2. Adverse medical outcomes (complications, mortality, relapse, intensive care unit [ICU] admission)
3. Antibiotic side effects
4. Length of hospital stay
5. Differences between procalcitonin (PCT) levels measured by KRYPTOR® and VIDAS®

All primary and secondary outcome measures will be assessed by a telephone interview 30 days after the start of the treatment.

Overall study start date
10/09/2009

Completion date
09/09/2011

Eligibility

Key inclusion criteria
1. Both males and females, age >18
2. Lower respiratory tract infection (at least one respiratory symptom [cough, sputum production, dyspnea, tachypnea, pleuritic pain]) PLUS
3. One of the following auscultatory finding or sign of infection:
3.1. Core body temperature >38°C or <36°C
3.2. Shivers
3.3. Leukocyte count >10 g/L or <4 g/L cells

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1,200

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
10/09/2009

Date of final enrolment
09/09/2011

Locations

Countries of recruitment
France

Switzerland

Study participating centre
Tellstrasse
Aarau
Switzerland
5001

Sponsor information

Organisation
BioMérieux (France)

Sponsor details
Chemin de l'Orme
Marcy l'Étoile
France
69280

Sponsor type

Industry

Website
http://www.biomerieux.com/servlet/srt/bio/portail/home

ROR
https://ror.org/03hf69k85

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Aarau Hospital (Switzerland)

Funder Name
BioMerieux (France) provides the procalcitonin test kits

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	14/05/2012		Yes	No