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	Recruitment status No longer recruiting	Prospectively registered		
18/09/2009		☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
16/10/2009		[X] Results		
Last Edited	Condition category	Individual participant data		
17/07/2012	Infections and Infestations			

Plain English summary of protocol

Not provided at time of registration

Study website

http://www.proreal.li/

Contact information

Type(s)

Scientific

Contact name

Dr Werner Albrich

Contact details

Tellstrasse Kantonsspital Aarau 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 q/L or <4 q/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