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Effectiveness of anti-inflammatory treatment versus antibiotic therapy and placebo in patients with acute bronchitis and purulent expectoration

Submission date 02/03/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 04/03/2011	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 28/10/2013	**Condition category** Respiratory	[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Ana Moragas

Contact details
Av. Horta de Santa Maria, 4, 3r 4a
Cambrils
Spain
43850
+34 (0)60 007 21 70
amoragasm@meditex.es

Additional identifiers

EudraCT/CTIS number
2007-006727-12

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
E07/90333

Study information

Scientific Title
Effectiveness of anti-inflammatory treatment versus antibiotic therapy and placebo in patients with acute bronchitis and purulent sputum: a double-blind randomised controlled clinical trial

Acronym
BAAP Study

Study objectives
The number of days of frequent cough (defined by the symptom diary with a score of 1 or more) among patients taking the anti-inflammatory drug will be fewer than among patients assigned to the other two arms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The Ethical Committee of Investigation in Primary Care (Fundació dInvestigació en Atenció Primària) approved on the 2nd of December 2007 (ref: P07/15)
2. Spanish Agency of Medicines and Health Products (Agencia Española de Medicamentos y Productos Sanitarios [AEMPS]) and the EudraCT approved (ref: 2007-006727-12)

Study design
Double blind randomised controlled clinical 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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Acute bronchitis and purulent sputum

Interventions

The patients will be randomised with simple random numbers to one of the three following treatment arms:
1. Ibuprofen 600 mg/8 hours, during 10 days, taken after meals
2. Amoxycillin plus clavulanic acid 500-125 mg/8 hours, during 10 days, taken after meals
3. Placebo, one tablet every 8 hours, during 10 days, taken after meals

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Number of days with frequent cough

Secondary outcome measures
Secondary result variables considered will be the efficacy of the treatment, the time of symptom resolution, the reduction in the total daily score of the symptom diary and the secondary effects and adverse reactions which may present with the three treatment arms. With regard to efficacy, three outcomes will be distinguished: cure, defined as the disappearance of the acute signs and symptoms related to the infection (complete return to the previous situation of stability), improvement, defined as the non complete resolution of the symptoms and failure, with an insufficient reduction in the signs and symptoms of infection.

Overall study start date
01/04/2010

Completion date
31/03/2011

Eligibility

Key inclusion criteria
Patients from 18 to 70 years of age without associated respiratory comorbidity or immunosuppression will be recruited from seven healthcare centers in Catalonia.
1. Presenting respiratory infection of at least one week of evolution
2. Cough as the predominant symptom
3. Presence of purulent expectoration of at least one week of duration
4. At least one other respiratory tract symptom such as dyspnoea, wheezing, chest discomfort or pain, with no alternative explanation such as pneumonic condensation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
Total of 420 patients

Key exclusion criteria
1. Patients less than 18 and older than 70 years of age
2. Presence of radiological signs of pneumonia
3. Signs of severe infection
3.1. confusion
3.2. tachypnoea > 25 respirations per minute of tachycardia > 120 beats per minute
4. History of digestive haemorrhage or intolerance to anti-inflammatory treatment
5. Hypersensitivity to β-lactam or intolerance to clavulanic acid or lactose
6. Pregnancy, lactation and women of fertile age not using contraceptive measures
7. Antibiotic, anti-inflammatory or corticoid use in the previous two weeks
8. Associated comorbidity
8.1. bronchial asthma
8.2. chronic obstructive pulmonary disease
8.3. moderate-severe heart failure
8.4. dementia
8.5. stroke
8.6. immunosupression or the use of immunosuppressive drugs
9. Emergency situation
10. Institutionalisation in a residence
11. And/or subjects unable to personally provide informed consent

Date of first enrolment
01/04/2010

Date of final enrolment
31/03/2011

Locations

Countries of recruitment
Spain

Study participating centre
Av. Horta de Santa Maria, 4, 3r 4a
Cambrils
Spain
43850

Sponsor information

Organisation
Primary Care Research Institute Jordi Gol i Gurina (Institut dInvestigació en Atenció Primària Jordi Gol i Gurina) (Spain)

Sponsor details
Av. Gran Via de les Corts Catalanes
587, Àtic
Barcelona
Spain
08007
+34 (0)93 482 41 24
cviolan@idiapjgol.org

Sponsor type
Government

Website
http://www.idiapjgol.org

ROR
https://ror.org/0370bpp07

Funder(s)

Funder type
Government

Funder Name
Health Research Fund of the Ministry of Health and Consumption (Fondo de Investigación Sanitaria de Ministerio de Sanidad y Consumo) (Spain) (EC07/90333)

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	21/06/2011		Yes	No
Results article	results	04/10/2013		Yes	No