

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

<b>Submission date</b> 02/03/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 04/03/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 28/10/2013	<b>Condition category</b> 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

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 d'Investigació 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  $\beta$ -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. immunosuppression 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 d'Investigació en Atenció Primària Jordi Gol i Gurina) (Spain)

## Sponsor details

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## 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?
<a href="#">Protocol article</a>	protocol	21/06/2011		Yes	No
<a href="#">Results article</a>	results	04/10/2013		Yes	No