

# Effect of corticosteroid adjunctive therapy on the clinical course and outcome of severe community-acquired pneumonia (CAP): a randomised, double-blinded study

<b>Submission date</b> 03/08/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 05/10/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/07/2012	<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

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

FIS Grant 99/0838 and AEM 99/0145

## **Study information**

**Scientific Title**

**Study objectives**

In our study we try to demonstrate if a corticosteroid adjuvant therapy (CAT), consisting of a bolus of methylprednisolone (MPDN) given prior to antibiotic treatment followed by a sustained infusion for 9 days, modulates the inflammatory response and improves the clinical outcome of CAP presenting with respiratory failure and extensive radiological changes.

**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)**

Not specified

**Study type(s)**

Treatment

**Participant information sheet**

**Health condition(s) or problem(s) studied**

Severe community-acquired pneumonia

**Interventions**

All patients received intravenous antibiotic treatment consisting of 1 g per day of ceftriaxone and 500 mg/day of levofloxacin. In addition, a bolus of 200 mg of MPDN or placebo was administered, 30 minutes before starting the antibiotic treatment. Thereafter, a maintenance intravenous dose (20 mg/6 hours) was given for three days, then 20 mg/12 hours for three days, and finally 20 mg/day for another three days.

**Intervention Type**

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Methylprednisolone

**Primary outcome measure**

The presence of respiratory failure needing conventional mechanical ventilation (MV) or non-invasive positive pressure ventilation (NPPV), was selected as primary outcome of the study.

**Secondary outcome measures**

1. Eventual differences in relation to other main variables relative to the outcome, such as days in hospital, need and duration of intensive care unit (ICU) stay and mortality
2. Differences in the inflammatory response measured in venous blood

**Overall study start date**

01/01/2000

**Completion date**

31/12/2002

## **Eligibility**

**Key inclusion criteria**

Community-acquired pneumonia (CAP) presenting extensive radiographic consolidations (affecting entirely at least two lobes), and respiratory failure ( $pO_2/FiO_2 < 300$ ).

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

56

**Key exclusion criteria**

Exclusion criteria included:

1. Age  $< 18$  years and  $> 75$  years
2. No written informed consent available
3. Known hypersensitivity to steroids
4. Steroid treatment in the previous 48 hours
5. Need of steroid treatment for any reason (asthma, chronic obstructive pulmonary disease [COPD] etc.)
6. Uncontrolled diabetes mellitus

7. Active peptic ulcer
8. Active Mycobacterial or fungal infection
9. Reported severe immunosuppression
10. Hospital admission during the previous 8 days
11. Empyema
12. Extrapulmonary septic manifestations
13. Presence of shock
14. Need of mechanical ventilation prior to the inclusion into the study

**Date of first enrolment**

01/01/2000

**Date of final enrolment**

31/12/2002

## **Locations**

**Countries of recruitment**

Spain

**Study participating centre**

**Servei de Pneumologia**

Barcelona

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## **Sponsor information**

**Organisation**

Institute of Health Carlos III (Instituto de Salud Carlos III) (Spain)

**Sponsor details**

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**Sponsor type**

Government

**Website**

<http://www.isciii.es>

ROR

<https://ror.org/00ca2c886>

## Funder(s)

### Funder type

Government

### Funder Name

Institute of Health Carlos III (Instituto de Salud Carlos III) (Spain) (FIS grant 99/0838)

### Funder Name

Red Respira (Spain) (ref: ISCIII RTIC 03/11)

## 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="#">Results article</a>	results	15/03/2011		Yes	No