

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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Spain

08907

Sponsor information

Organisation

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

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

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? |
|-------------|---------|--------------|------------|----------------|-----------------|
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[Results article](#)

results

15/03/2011

Yes

No