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

Submission date
03/08/2005

Recruitment status
No longer recruiting

Registration date
05/10/2005

Overall study status
Completed

Last Edited
09/07/2012

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 inflamatory 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 (NNPV), 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 (pO2/FiO2 <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 imunosuppresion
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)

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?
Results article	results	15/03/2011		Yes	No