

Use of corticosteroids in pulmonary leptospirosis: a randomised double-blind clinical trial

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| Submission date 25/03/2008 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 16/05/2008 | Overall study status Completed | <input checked="" type="checkbox"/> Protocol |
| Last Edited 23/10/2020 | Condition category Infections and Infestations | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
FR-167386

Study information

Scientific Title
Use of corticosteroids in pulmonary leptospirosis: a randomised double-blind clinical trial

Acronym

ARDS

Study objectives

Pulse therapy with corticosteroids leads to better results in pulmonary leptospirosis, reducing pulmonary infiltrate, occurrence of pulmonary haemorrhage, number of days in mechanical ventilation, incidence of acute respiratory failure, occurrence of secondary respiratory infection and mortality.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical Committee of Research, Health Science Department, Federal University of Pernambuco (Comitê de Ética em Pesquisa, Centro de Ciências da Saúde, Universidade Federal de Pernambuco) Date of approval: 22/02/2008 (ref: CEP/CCS/UFPE N° 416/07)

Study design

Randomised, double-blind, controlled trial.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Leptospirosis

Interventions

Patients will be randomised to either methylprednisolone or placebo in blocks of four according to a random number generator. The randomisation ratio was 2 (methylprednisolone) to 1 (placebo). The participants and the medical staff were blinded throughout the study.

Intervention group: 1 g methylprednisolone per day intravenously for three consecutive days

Control group: Placebo intravenously for three consecutive days

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Methylprednisolone

Primary outcome(s)

Mortality, recorded during the whole hospitalisation period.

Key secondary outcome(s)

1. Outcome of pulmonary leptospirosis after corticosteroids administration, assessed during the first seven days and then on the 14th and 28th day, by clinical and radiological assessment, and PaO₂/FiO₂ and haemoglobin/haematocrit evaluation.
2. Number of days in mechanical ventilation
3. Number of days in hospital
4. Number of days in UCI
5. Respiratory infection, monitored during the first seven days and then on the 14th and 28th day, by clinical and radiological assessment, and PaO₂/FiO₂ and leukocyte evaluation.
6. Other respiratory complications, monitored during the first seven days and then on the 14th and 28th day, by clinical and radiological assessment, and the PaO₂/FiO₂ evaluation.
7. Other infectious complications, monitored during the first seven days and then on the 14th and 28th day
8. Adverse events associated with corticosteroid administration, monitored during the first seven days and then on the 14th and 28th day

Completion date

31/12/2009

Eligibility

Key inclusion criteria

1. Both males and females
2. Diagnosis of leptospirosis: Abrupt fever and myalgia, jaundice, normal number of leucocytes or increased number of leucocytes, thrombocytopenia, high levels of muscle enzymes and lack of hyperkalemia
3. Diagnosis of pulmonary leptospirosis: Interstitial pulmonary infiltrate or alveolo interstitial bilateral, associated with at least one of the following:
 1. Changes in respiratory
 2. Cough
 3. Dyspnea
 4. Decrease of haemoglobin
 5. Haemoptysis
 6. Hypoxemia (PO₂/FiO₂ <300)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Age under 15 years old
2. History of hypersensitivity to corticosteroids
3. Pregnancy
4. History of active tuberculosis or fungal infection

5. Recent history of head trauma
6. Neurosurgery
7. Peptic ulcer disorder
8. Enrolled in another trial

Date of first enrolment

01/04/2008

Date of final enrolment

31/12/2009

Locations

Countries of recruitment

Brazil

Study participating centre

Rua Professor Augusto Lins e Silva

Recife

Brazil

81030-030

Sponsor information

Organisation

Federal University of Pernambuco (Universidade Federal de Pernambuco [UFPE]) (Brazil)

ROR

<https://ror.org/047908t24>

Funder(s)

Funder type

University/education

Funder Name

Federal University of Pernambuco (Universidade Federal de Pernambuco [UFPE]), Clinical Hospital (Brazil)

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? |
|----------------------------------|----------|--------------|------------|----------------|-----------------|
| Protocol article | protocol | 30/06/2011 | 23/10/2020 | Yes | No |