

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

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

### Contact name

Dr Ana Flávia Azevedo

### Contact details

Rua Professor Augusto Lins e Silva  
228/901  
Boa Viagem  
Recife  
Brazil  
81030-030

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## 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 measure**

Mortality, recorded during the whole hospitalisation period.

## **Secondary outcome measures**

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 PaO<sub>2</sub>/FiO<sub>2</sub> 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 PaO<sub>2</sub>/FiO<sub>2</sub> 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 PaO<sub>2</sub>/FiO<sub>2</sub> 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

## **Overall study start date**

01/04/2008

## **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 ( $PO_2/FiO_2 < 300$ )

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

266 patients

**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)

## Sponsor details

Av. Prof. Moraes Rego  
1235  
Cidade Universitária  
Recife  
Brazil  
50670-901

## Sponsor type

University/education

## Website

<http://www.ufpe.br>

## 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

### 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	30/06/2011	23/10/2020	Yes	No

