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

Submission date	Recruitment status	[_] Prospectively registered
25/03/2008	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/05/2008	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
23/10/2020	Infections and Infestations	[_] 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

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 Nº 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 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

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 (PO2/FiO2 <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
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Brazil
81030-030

Sponsor information

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

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