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A phase II trial to investigate the safety of early high dose methylprednisolone in acute leprous neuritis and leprosy type 1 reactions with neuritis in Nepal

Submission date
04/12/2005

Registration date
04/04/2006

Last Edited
03/02/2016

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Leprosy is caused by a bacterium and is curable with a combination of antibiotics known as multi-drug therapy that patients take for 6 or 12 months. However, many leprosy patients experience inflammation in their skin and/or nerves, which may occur even after successful completion of multi-drug therapy. These episodes of inflammation are called leprosy Type 1 reactions. Type 1 reactions are an important complication of leprosy because they may result in nerve damage that leads to disability and deformity. Type 1 reactions require treatment with immunosuppressive agents such as corticosteroids. The best dose and duration of corticosteroid treatment is currently unclear. The aim of this study is to see if it would be safe to use a large dose of a corticosteroid called methylprednisolone for three days at the start of 16 weeks of treatment with the corticosteroid prednisolone.

Who can participate?
Patients age 16-65 with leprosy Type 1 reactions and nerve damage present for less than six months.

What does the study involve?
Participants are randomly allocated to one of two groups. One group is treated with methylprednisolone intravenously (given into a vein) and placebo (dummy) tablets for the first three days of treatment. The other group is treated with a placebo intravenous infusion and prednisolone tablets for the first three days of treatment. Both groups are then treated with prednisolone tablets for 16 weeks.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
London School of Hygiene and Tropical Medicine (UK)

When is the study starting and how long is it expected to run for?
December 2005 to December 2007

Who is funding the study?
LEPRA (UK), American Leprosy Mission (USA), Hospital for Tropical Diseases London (UK)

Who is the main contact?
Dr Diana Lockwood
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
4022

Study information

Scientific Title
A phase II trial to investigate the safety of early high dose methylprednisolone in acute leprous neuritis and leprosy type 1 reactions with neuritis in Nepal

Acronym
MPSTUDY

Study objectives

Early high dose steroids will improve recovery of acute neuritis and prevent relapse

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. London School of Hygiene and Tropical Medicine, 28/11/2005, ref: 4022
2. Nepal Medical Research Council

Study design
Randomised double-blind trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Leprosy

Interventions
Study arm receives intravenous (IV) methylprednisolone in the first three days of type 1 reaction or acute neuritis treatment. The control arm receives a standard treatment of 40 mg prednisolone plus a normal saline (placebo) infusion. Those receiving IV methylprednisolone are given placebo tablets to ensure complete blinding. The following sixteen weeks of treatment are identical for both groups.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Methylprednisolone, prednisolone

Primary outcome measure
Nerve function

Secondary outcome measures
Amount of additional steroid required

Overall study start date
07/12/2005

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. Those with type 1 reaction with new nerve function impairment
2. Age 16-65 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Type 1 reaction without new nerve function impairment
2. Systemic corticosteroids in the preceding three months
3. Contraindications to steroids
4. Pregnancy
5. Severe active infection
6. Severe intercurrent illness

Date of first enrolment
07/12/2005

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
England

Nepal

United Kingdom

Study participating centre
London School of Hygiene and Tropical Medicine
London
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Sponsor information

Organisation
London School of Hygiene and Tropical Medicine (UK)

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Sponsor type
University/education

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Charity

Funder Name
LEPRA (UK)

Funder Name
American Leprosy Mission (USA)

Funder Name

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	12/04/2011		Yes	No
Results article	results	01/04/2012		Yes	No