Multicentre field trial of ofloxacin-containing Multidrug Therapy (MDT) in leprosy (Philippines)

Submission date	Recruitment status No longer recruiting	Prospectively registered	
05/04/2005		☐ Protocol	
Registration date 07/06/2005	Overall study status Completed	Statistical analysis plan	
		Results	
Last Edited 26/03/2008	Condition category Infections and Infestations	Individual participant data	
		Record updated in last year	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 920335

Study information

Scientific Title

Study objectives

Not provided at time of registration

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

Leprosy

Interventions

Therapeutic efficacy of new MDT regimen containing Ofloxacin, in comparison with the standard World Health Organization (WHO)/MDT regimen among paucibacillary (PB) and multibacillary (MB) leprosy patients.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Ofloxacin

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

08/04/2003

Completion date

31/12/2004

Eligibility

Key inclusion criteria

All patients suspected of leprosy without previous treatments with MDT or ofloxacin in dermatological consultation and referred to the Leprosy Unit.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Not provided at time of registration

Key exclusion criteria

- 1. Patients with provincial addresses, temporary addresses and temporary works
- 2. Patients not residing in targeted areas for the study

Date of first enrolment

08/04/2003

Date of final enrolment

31/12/2004

Locations

Countries of recruitment

Philippines

Switzerland

Study participating centre 20, Avenue Appia

Geneva -27 Switzerland CH 1211

Sponsor information

Organisation

UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR)

Sponsor details

20, Avenue Appia Geneva -27 Switzerland CH 1211

Sponsor type

Research organisation

Website

http://www.who.int

ROR

https://ror.org/01f80g185

Funder(s)

Funder type

Research organisation

Funder Name

United Nations Children's Fund (UNICEF)/United Nations Development Programme (UNDP) /World Bank/World Health Organization (WHO) - Special Programme for Research and Training in Tropical Diseases (TDR)

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