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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr V.E. Pannikar

Contact details
20, Avenue Appia
Geneva -27
Switzerland
CH 1211
pannikerv@who.int

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