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A prospective (sero-)epidemiological study on contact transmission and chemoprophylaxis in leprosy

Submission date	Recruitment status	[_] Prospectively registered
19/12/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/12/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/03/2008	Infections and Infestations	

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
N/A

Study information

Scientific Title

Acronym
COLEP

Study objectives
Rifampicin is an effective chemoprophylactic intervention method to prevent leprosy among close contacts of leprosy patients.

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)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Leprosy

Interventions
All close contacts of 1000 consecutive new leprosy patients in the districts of Nilphamari and Rangpur (Bangladesh) who are recruited for the study are considered for inclusion. A contact group consists of around 20 individuals.

A single dose of rifampicin or a placebo is given to all included contacts. The rifampicin comes in capsules of 150 mg and the dosage is the same as recommended in the guidelines of the national leprosy control programme of Bangladesh and DBLM. According to bodyweight and age, two to four capsules are taken by the contact under direct supervision of a DBLM staff member. All the contacts of one patient receive medication from the same container.

Dosage of rifampicin according to age and body weight:
Adult greater than 35 kg: 600 mg
Adult less than 35 kg: 450 mg
Child 10 - 14 years: 450 mg
Child 5 - 9 years: 300 mg

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Rifampicin

Primary outcome measure
The primary outcome measure is the number of new leprosy patients emerging from the contact groups. The proportions between the rifampicin and the placebo group will be compared at two-years intervals.

Secondary outcome measures
Analysis will be carried out in order to define special groups at risk. The results of the serological tests will also be compiled and analysed. The number of leprosy patients found in the referent group will be used to calculate the prevalence rate (at intake) and the incidence rate (during follow-up) in the general population, allowing for calculation of relative risks among the contacts.

Overall study start date
01/05/2002

Completion date
31/10/2007

Eligibility

Key inclusion criteria
Patients should give consent for approaching their contacts for the trial.
Inclusion criteria for contacts:
1. Those living in the same house
2. Those living in a house sharing the same kitchen
3. First neighbours
4. Close business or social contacts, including other relatives. To be included into this category one has to be in contact with the patient on a daily base (five or more days a week) and during several hours a day.
5. Second neighbours

All divided into spouse, child, parent, sibling, other relative, relative-in-law, non-relative.

Participant type(s)

Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
20,000

Key exclusion criteria
Exclusion criteria for contacts:
1. Any contact who refuses to be included
2. Any contact being pregnant
3. Any contact currently on tuberculosis (TB) or leprosy treatment (however, released from treatment [RFT] patients should be included)
4. Any contact below 5 years of age
5. Any contact suffering from jaundice
6. Any contact living only temporarily in the area
7. Any contact found to suffer from leprosy at the initial survey
8. Any contact already enrolled in the study via the contact

Date of first enrolment
01/05/2002

Date of final enrolment
31/10/2007

Locations

Countries of recruitment
Bangladesh

Netherlands

Study participating centre
Erasmus Medical Centre Rotterdam
Rotterdam
Netherlands
3000 DR

Sponsor information

Organisation

Erasmus Medical Centre (The Netherlands)

Sponsor details
Department of Public Health
P.O. Box 1738
Rotterdam
Netherlands
3000 DR

Sponsor type
Hospital/treatment centre

Website
http://www.erasmusmc.nl/content/englishindex.htm

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Charity

Funder Name
The Leprosy Mission International (UK)

Funder Name
American Leprosy Missions (USA)

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	05/04/2008		Yes	No