

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

**Submission date**  
19/12/2005

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
19/12/2005

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
18/03/2008

**Condition category**  
Infections and Infestations

☐ Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

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

**Study type(s)**

Not Specified

**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(s)**

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.

**Key secondary outcome(s))**

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.

**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

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

Not Specified

**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)

**ROR**

<https://ror.org/018906e22>

## Funder(s)

**Funder type**

Charity

**Funder Name**

The Leprosy Mission International (UK)

**Funder Name**

## Results and Publications

### 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?
<a href="#">Results article</a>	Results	05/04/2008		Yes	No