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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27022

Source
NTR

Brief title
COLEP

Health condition

Leprosy is an infectious disease caused by Mycobacterium leprae, which is spread from person to person mainly through nasal discharges. Contacts of leprosy patients are known to have an increased risk of contracting leprosy.

Sponsors and support

Primary sponsor: Department of Public Health of the University Medical Center (Erasmus MC) Rotterdam, The Netherlands
KIT (Royal Tropical Institute) Biomedical Research, Amsterdam, The Netherlands
Danish Bangladesh Leprosy Mission (DBLM), Nilphamari, Bangladesh
Source(s) of monetary or material Support: American Leprosy Mission
The Leprosy Mission International

Intervention

Outcome measures

Primary outcome

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 2-years intervals.

Secondary outcome

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.

Study description

Background summary

N/A

Study objective

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

Study design

N/A

Intervention

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 (table). According to bodyweight and age, 2 to 4 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.Table: Dosage of rifampicin according to age and body weightAge/weight .

Dose of chemoprophylaxis.

Adult >35 kg: 600 mg;

Adult <35 kg: 450 mg;

Child 10-14 years: 450 mg;

Child 5-9 years; 300 mg.

Contacts

Public
Erasmus Medical Center Rotterdam, Department of Public Health,
P.O. Box 1738
F.J. Moet
Rotterdam 3000 DR
The Netherlands
Scientific
Erasmus Medical Center Rotterdam, Department of Public Health,
P.O. Box 1738
F.J. Moet
Rotterdam 3000 DR
The Netherlands

Eligibility criteria

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 (5 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.

Exclusion criteria

Exclusion criteria for contacts:

1. Any contact who refuses to be included;

2. Any contact being pregnant;

3. Any contact currently on TB or leprosy treatment (however, RFT-ed 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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2002

Enrollment:	20000
Type:	Actual

Ethics review

Positive opinion Date:	25-10-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL355
NTR-old	NTR394
Other	: N/A
ISRCTN	ISRCTN61223447

Study results

Summary results

Moet FJ, Oskam L, Faber R, Pahan D and Richardus JH. A study on transmission and a trial of chemoprophylaxis in contacts of leprosy patients: design, methodology and recruitment findings of COLEP. Lepr Rev 2004;75:376-88.