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

Gepubliceerd: 25-10-2005 Laatst bijgewerkt: 18-08-2022

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

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestopt |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON27022

**Bron**
Nationaal Trial Register

**Verkorte titel**
COLEP

**Aandoening**

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.

### Ondersteuning

**Primaire 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
**Overige ondersteuning:** American Leprosy Mission
The Leprosy Mission International

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

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.

# Toelichting onderzoek

### Achtergrond van het onderzoek

N/A

### Doel van het onderzoek

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

### Onderzoeksopzet

N/A

### Onderzoeksproduct en/of interventie

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.

# Contactpersonen

## Publiek

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

## Wetenschappelijk

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

# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Dubbelblind |
| Controle: | Placebo |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestopt |
| (Verwachte) startdatum: | 01-05-2002 |

| | |
|---|---|
| Aantal proefpersonen: | 20000 |
| Type: | Werkelijke startdatum |

## Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 25-10-2005 |
| Soort: | Eerste indiening |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

| Register | ID |
|---|---|
| NTR-new | NL355 |
| NTR-old | NTR394 |
| Ander register | : N/A |
| ISRCTN | ISRCTN61223447 |

## Resultaten

**Samenvatting resultaten**

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.