The combined effect of a single dose of rifampicin and vaccination with BCG, in the prevention of leprosy in contacts of newly diagnosed cases: A randomized controlled trial.

Gepubliceerd: 28-09-2011 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24868

Bron
NTR

Verkorte titel
MALTALEP study

Aandoening

Leprosy

Ondersteuning

Primaire sponsor: - Erasmus MC, University Medical Center Rotterdam
Department of Public Health
- The Leprosy Mission International Bangladesh
Overige ondersteuning: The order of MALTA Grants for LEProsy research: MALTALEP
42, rue des Volontaires
F-75015 Paris

France

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

New cases of leprosy among the contacts of index cases.

Toelichting onderzoek

Achtergrond van het onderzoek

Despite almost 30 years of effective chemotherapy with highly bactericidal drugs (MDT), the incidence of leprosy has remained rather constant up to now. It appears likely that transmission to contacts occurs before treatment is started, and that new tools and methodologies will be needed to interrupt it. Single-dose rifampicin has been shown to prevent 56% of incident cases of leprosy in the first two years, when given to contacts of newly diagnosed cases. Immunization of contacts with BCG has been less well documented, but appears to have a preventive effect lasting up to 9 years; one major disadvantage is the precipitation of excess cases within the first year after immunization. We hypothesize that these two forms of prophylaxis could be complementary, producing a more pronounced preventive effect when given together. We propose a cluster randomized controlled trial in northwest Bangladesh, to compare BCG alone with BCG plus rifampicin, in contacts of new leprosy cases; the intervention group will be given BCG followed by rifampicin, 2 months later. In total 10,000 contacts will be included in each intervention arm. Follow-up will take place over the following one year. The outcome is the occurrence of clinical leprosy within this year.

Doel van het onderzoek

Single-dose rifampicin has been shown to prevent 56% of incident cases of leprosy in the first two years, when given to contacts of newly diagnosed cases. Immunization of contacts with BCG has been less well documented, but appears to have a preventive effect lasting up to 9 years; one major disadvantage is the precipitation of excess cases within the first year after immunization. We hypothesize that these two forms of prophylaxis could be complementary, producing a more pronounced preventive effect when given together.

Onderzoeksopzet

After one year the number of new cases of leprosy among contacts of the index patients will be evaluated.

During the follow up visits after two month and one year, participants will get a physical examination to check for signs and symptoms of leprosy. All participants who are diagnosed in regular clinics in between the follow up visits will be registered as well. A medical officer will confirm all new cases of leprosy.

Onderzoeksproduct en/of interventie

At intake: BCG vaccination will be given to all contacts of leprosy patients included in the study.
During a follow-up visit two months later: participants will be checked for symptoms and signs of leprosy. A single dose of rifampicin will be provided to the participants in one arm of the study, while participants in the other arm will only receive the health check.

During a follow up visit after one year, all participants will be checked for symptoms and signs of leprosy.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Around 1,300 consecutive leprosy patients will be enrolled. The diagnosis of leprosy is

generally carried out according to the RHP guidelines, which follow those of the national leprosy control program. A medical officer confirms all leprosy cases included in the study, and this confirmation is written on the patient card.

For the 1,300 consecutive new leprosy patients, contact groups will be formed consisting of around 15 persons for each patient. Thus the total number of contacts who will be considered for inclusion will be around 20,000.

The following categories of contacts have been distinguished:

1. Those living in the same house (household members);

2. Those living in a house on the same compound, sharing the same kitchen;

3. Direct neighbors (first neighbors).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria for patients are as follows:

1. Any patient who refuses examination of contacts;

2. Any patient who suffers from the pure neural form of leprosy;

3. Any patient who resides only temporarily in the study area;

4. Any new patient found during contact examination of the index case;

5. Any new patient living less than six houses (or less than 100 m) away from a patient already included in the study;

6. First and second degree relatives of a patient already included in the study.

Exclusion criteria for contacts are as follows:

1. Any person who refuses informed consent;

2. Any woman indicating that she is pregnant;

3. Any person who had leprosy in the past or is currently on leprosy treatment;

4. Any person who had TB in the past or is currently on TB treatment;

5. Any person below 5 years of age;

6. Any person known to suffer from liver disease or jaundice;

7. Any person known to suffer from impaired immunity for example due to HIV, malignancies or the use of steroids;

8. Any person residing temporarily in the area;

9. Any person suffering from leprosy at the initial survey (these patients will be referred to the clinic for leprosy treatment);

10. Any person who is a contact of another patient and is already enrolled in the contact group of the other patient.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	15-10-2011
Aantal proefpersonen:	20000
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	28-09-2011
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	NL2940
NTR-old	NTR3087
Ander register	Bangladesh Medical Research Council : BMRC/NREC/2010-2013/1534
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A