Chemoprophylaxis for leprosy: comparing the effectiveness and feasibility of a skin camp intervention to a health centre-based intervention

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27622

Source
Nationaal Trial Register

Brief title
PEP4LEP

Health condition

Leprosy, lepra, Hansen's disease, skin diseases, dermatological conditions, NTDs

Sponsors and support

Primary sponsor: This project was supported by the EDCTP2 program under Horizon 2020 (grant number RIA2017NIM-1839-441 PEP4LEP). The project also received funding from the Leprosy Research Initiative (LRI; www.leprosyresearch.org) under LRI grant number 707.19.58.
Source(s) of monetary or material Support: This project was supported by the EDCTP2 program under Horizon 2020 (grant number RIA2017NIM-1839-441 PEP4LEP). The project also received funding from the Leprosy Research Initiative (LRI; www.leprosyresearch.org) under LRI grant number 707.19.58.

Intervention

Outcome measures

Primary outcome

• To compare the effectiveness of a skin camp prophylaxis intervention to a health centre-based prophylaxis intervention in terms of the rate of leprosy patients detected and delay in case detection
• To compare the feasibility of the two chemoprophylaxis interventions (screening household contacts or screening contact via skincamp) in terms of cost effectiveness and acceptability

Secondary outcome

• To assess the acceptability of a common skin diseases approach and the use of the SkinApp
• To compare the capacity of health workers in diagnosing leprosy and other NIDs that manifest with skin lesions before the start of the study with their capacity in the third year

Study description

Background summary

The project PEP4LEP - Chemoprophylaxis for leprosy: comparing the effectiveness and feasibility of a skin camp intervention to a health centre-based intervention, will perform an implementation trial in Mozambique, Ethiopia and Tanzania. The aim of the trial is to contribute to interrupting the transmission of M. leprae by identifying the most effective and feasible method of screening people at risk of developing leprosy and administering chemoprophylaxis in Ethiopia, Mozambique and Tanzania.

The primary objectives are:
• To compare the effectiveness of a skin camp prophylaxis intervention to a health centre-based prophylaxis intervention in terms of the rate of leprosy patients detected and delay in case detection
• To compare the feasibility of the two chemoprophylaxis interventions in terms of cost effectiveness and acceptability

The secondary objectives are:
• To assess the acceptability of a common skin diseases approach and the use of the SkinApp
• To compare the capacity of health workers in diagnosing leprosy and other NIDs that manifest with skin lesions before the start of the study with their capacity in the third year

The objectives will be achieved using a two-arm, clustered-randomized implementation trial design, comparing two interventions for screening of contacts of leprosy patients and

distribution of single-dose rifampicin (SDR) as chemoprophylaxis. Both interventions are based on the evidence that contacts of leprosy patients, household contacts as well as neighbours, have a higher risk of developing leprosy. SDR has been proven to reduce the risk of developing leprosy with 60% when given to contacts of leprosy patients.

One intervention will be community based, using skin camps to screen around 100 contacts of leprosy patients and provide them with SDR when eligible. The other intervention will be health centre-based, inviting household contacts to be screened and given SDR when eligible. Both interventions will use a common skin diseases approach; other skin diseases, such as common skin diseases and neglected infectious diseases (NIDs) manifesting skin lesions, will also be diagnosed and treated. In this way, the project will contribute to health system strengthening in the area of diagnosis and treatment of dermatological conditions.

Both interventions will be compared against a baseline. They will be compared in terms of effectiveness by looking at the rate of leprosy patients detected and the delay in case detection. The feasibility of the two interventions will be evaluated by assessing the acceptability of the two interventions and by comparing cost-effectiveness.

This study will translate a medical intervention of proven efficacy (SDR) into routine care. Because of the feasibility component and the development of guidelines as part of the study, the results can be presented for uptake in national and international policies. Upscaling chemoprophylaxis for leprosy will have a major impact because it will contribute to interrupting the transmission of M. leprae.

PEP4LEP study consortium:
- Nederlandse Stichting voor Leprabestrijding (NLR), the Netherlands
- Erasmus Universitair Medisch Centrum Rotterdam (‘Erasmus MC’), the Netherlands
- Deutsche Lepra- und Tuberkulosehilfe e. v. (DAHW, GLRA), Germany
- Federal Democratic Republic of Ethiopia Ministry of Health (FMOH), Ethiopia
- Armauer Hansen Research Institute (AHRI), Ethiopia
- Ministerio de Saúde – Mozambique, Mozambique
- Universidade Lúrio, Mozambique
- Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDEC) - Tanzania, United Republic of Tanzania
- Catholic University of Health and Allied Sciences (CUHAS), United Republic of Tanzania

Ethical approval has been obtained:
- Ethiopia: National Research Ethics Review Committee from the Ministry of Science and Higher Education (MoSHE) - 17 February 2020
- Mozambique: Comité Nacional de Bioética para a Saúde (CNBS) from the Ministério da Saúde - 16 August 2019
- Tanzania: Ethical Clearance Committee linked to the National Institute for Medical Research (NIMR) and Ministry of Health, Community Development, Gender, Elderly & Children (MoHCDEC) - 17 June 2019
- A waiver was obtained from the Medical Ethics Committee Erasmus University Medical Center Rotterdam, the Netherlands - 11 April 2019

Study objective

Implementation of chemoprophylaxis can contribute to reducing the transmission by reducing the risk of developing the disease and by the early identification of new patients.The aim of the study is to contribute to interrupting the transmission of M. leprae by identifying the most effective and feasible method of screening people at risk of developing leprosy and administering chemoprophylaxis in Ethiopia, Mozambique and Tanzania.

Study design

The project will run for 52 months from the date of the formal launch (1 October 2018), but a project delay of at least 1 year because of COVID-19 is expected. The participant inclusion period is estimated to be 2.5 years.

Intervention

One intervention will be community based, using skin camps to screen around 100 contacts of an leprosy index patients and provide them with SDR-PEP when eligible. The other intervention will be health centre-based, inviting household contacts (approximatly 6 per leprosy index patient) to be screened and given SDR-PEP when eligible. Both interventions will use a common skin diseases approach; other skin diseases, such as common skin diseases and neglected tropical diseases (NTDs) manifesting skin lesions, will also be diagnosed and treated. The project will contribute to health system strengthening in the area of diagnosis and treatment of dermatological conditions.

Contacts

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Eligibility criteria

Inclusion criteria

Index patients:
- Consent to participate in the PEP4LEP project
- Diagnosed with leprosy (preferred maximum of 6 months prior to inclusion)
- Residence in the PEP4LEP districts for ≥3 months prior to the date of diagnosis
- Index patient has started MDT
- Community-based skin camp intervention: Leprosy patient gives permission for the set-up of a skin camp in his/her community (sharing their leprosy diagnosis with their contacts is not needed)
- Health center-based household screening intervention: Leprosy patient with household contacts, and who is willing to inform these contacts about PEP4LEP

Contacts:
- Consent to participate in the PEP4LEP project
- Community-based skin camp intervention: Community contact of the index patient for ≥3 months
- Health center-based household screening intervention: Contact which is a household member of the index patient for ≥3 months, visiting the screening health center ≤3 months after the index patient was included

The eligibility criterium for aditional stakeholders (community leaders, health workers, community health volunteers and health policy decision maker, contacts refusing SDR-PEP) taking part in the acceptability evaluation and the capacity assessment is providing consent to participate in the PEP4LEP project

Exclusion criteria

Index patients:
- Index patient or parents/legal guardians unable to understand the purpose and risks of participating in the PEP4LEP study

Contacts:
- Contact or parents/legal guardians unable to understand the purpose and risks of participating in the PEP4LEP study
- Age <2 years and/or <10 kg of weight*
- Pregnancy*
- Receiving or having received rifampicin for any reason in the last 2 years
- Known allergy to rifampicin
- History of liver or renal disorders
- Individuals with leprosy and those who have possible signs and/or symptoms of leprosy (e.g., leprosy-like skin lesions or nerve manifestations) until their disease status has been clarified**
- Individuals with possible signs and/or symptoms of TB (cough for more than two weeks or cough in known HIV/AIDS patients, night sweats, unexplained fever, weight loss) until their

disease status has been clarified ***
- Individuals with possible signs and/or symptoms of COVID-19 (self-assessed temperature ≥38°C, respiratory or cold-like symptoms, sudden loss of smell/taste) or possible contact with a COVID-19 patient in the past 14 days***

* A voucher will be given for repeated skin screening and SDR-PEP. This can be used in a PEP4LEP affiliated health center when this person becomes eligible (e.g., after giving birth)
** If referral was needed and no leprosy is detected, repeated skin screening and SDR-PEP can be provided in a PEP4LEP affiliated health center
*** Skin screening and SDR-PEP can only be provided in a PEP4LEP affiliated health center after the contact is tested negative for COVID-19/TB (according to national guidelines)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2019
Enrollment:	30000
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
Pseudonymised data entry of completed paper-based forms includes information about participants. The forms consist of: patient registration forms, contact registration forms, Case Detection Delay questionnaires and capacity assessment forms. Completed participant study information is to be uploaded into a centralised database server hosted by Erasmus MC.

To ensure data security, virtual machines (VM) will be set up for each country and will be integrated with the REDCap data capture software and database installed in a secure digital

data entry environment closed off from the internet. These VMs can be accessed by assigned users in each study country. Login details will be issued to authorised research staff to input data digitally from paper-based forms.

PEP4LEP data can only be shared between participating countries and Erasmus MC following the signing of a data transfer agreement (DTA) between the two parties.

Within REDCap, data access groups will be assigned so that data can only be input and managed at the country-level. The study will be set up as three separate projects within REDCap:

1. PEP4LEP – Skin Camp Group
2. PEP4LEP – Household Screening Group
3. PEP4LEP – Capacity Assessment

The Data Manager will act as the administrator for the software and will be able to monitor the data entry across the different study sites. Data can be exported using the data export tool into different formats (e.g. csv, spss) and saved on the VM shared drive (Z:/). These files will not be able to be downloaded from the VM without approval from the workspace Owner.

There are two user groups in the virtual environment:

1. Owners
2. Researchers

Only Owners have administrative rights in the VM, meaning that only they can approve download/retrieval of data and files within the secure virtual environment. Requests can be made by Researchers which will send an email request to the Owner.

Monthly data exports in each country will be performed at the country level by the Data Manager. These files will be aggregated and stored in Excel and/or SPSS as password protected backups on the Erasmus MC institute shared drive until interim and final data analyses are performed.

Qualitative data collected in the supporting studies will be kept confidential. Key informant interviews, potential observations and focus group discussion (FGD) data will be reported only by generic identifying characteristics, (i.e. gender, age). Interviewers will be trained on confidentiality procedures and sign for confidentiality as part of their employment agreement.

The data is owned by the countries of origin of the data and secondary to the PEP4LEP Project consortium. Access to the national virtual servers will be limited only to those authorised to do so by the institutional research coordinators. The Data Manager will grant additional privileges to authorised study personnel (e.g. investigators and health officials) in each participating country to ensure that partners have full access to their own data at all times.

Ethics review

Positive opinion

Date:	10-09-2018
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	NL7294
NTR-old	NTR7503
Other	RIA2017NIM-1839-441 : EDCTP

Study results

Summary results

Open access papers expected during/after finalizing the project