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# Use of honey for the treatment of leprosy ulcer

**Submission date**
16/11/2021

**Recruitment status**
No longer recruiting

**Registration date**
22/12/2021

**Overall study status**
Completed

**Last Edited**
31/12/2024

**Condition category**
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

## Plain English summary of protocol

Background and study aims
As in diabetes, ulcers in leprosy result from nerve damage and the resulting loss of sensation. Neuropathy in leprosy is caused primarily by inflammatory 'reactions', which occur in 30-50% of leprosy cases. Neuritis (nerve inflammation) can develop at any time before, during or even years after leprosy treatment. The combination of loss of sensation and deformities leads to recurrent ulcers and these often present when they are advanced. People afflicted with recurrent ulcers suffer severe consequences in terms of loss of function, loss of earnings and stigma, frequently becoming chronically depressed and withdrawn. This study evaluates a promising intervention to promote healing for leprosy ulcers. The use of honey to treat wounds is an ancient practice. Although there is a sizeable number of reports that show mixed levels of effectiveness in the use of honey for the treatment of different types of wounds, there is a lack of reports on the use of honey in the treatment of ulcers in leprosy. This study will evaluate the healing properties of raw, undiluted African honey in comparison with normal saline (saltwater) dressing of leprosy ulcers.

Who can participate?
Patients aged 18 years and above with chronic foot ulcers due to leprosy neuropathy (ulcer surface area 2-20 $cm^2$)

What does the study involve?
Participants will be randomly assigned to treatment with either honey or normal saline on their foot ulcers twice a week until the wound is completely healed. The participants will be asked to wear pedometers on the foot to determine whether their level of physical activity influences the healing process or not.

What are the possible benefits and risks of participating?
The possible benefit to the participants is that their ulcers will be treated at no cost. The possible risks to participating in this study are minimal because the intervention (honey) is a well-known traditional agent for the treatment of wounds. The Leprosy Mission Nigeria will provide a non-negligence insurance cover to the study participants.

Where is the study run from?
The study will be run from The Leprosy Referral Hospital Chanchaga, Minna, Niger state, and will be run by The Leprosy Mission Nigeria.

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Paul Tsaku
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# Contact information

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Scientific

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Public

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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
Nil known

# Study information

### Scientific Title
Honey Experiment on LeProsy Ulcer (HELP): a randomised control trial of raw, unadulterated African honey for ulcer healing in leprosy

### Acronym
HELP

### Study objectives
To evaluate the healing properties of raw, undiluted African honey in comparison with normal saline dressing of leprosy ulcers.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
1. approved 06/10/2021, Niger State Government Ministry of Health Research Ethics Committee (Block 'C' First Floor, Abdul-Kareem Lafene Secretariat Complex, Paiko Road, PMB 57, Minna, -, Nigeria; +234 (0)8038246018; ngsmohmx@yahoo.com), ref: STA/495/Vol/199

2. approved 19/01/2022, National Health Research Ethics Committee (Abuja, Abuja, -, Nigeria; +23495238367; info@nhrec.net), ref: FHREC/2022/01/09/04-02-22

### Study design
Multi-centre comparative prospective single-blind parallel-group 1:1 individually randomized controlled trial

### Primary study design
Interventional

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Leprosy ulcer

### Interventions
Participants will be enrolled sequentially and randomly allocated (1:1) to undergo honey treatment or usual care with normal saline using a “digital sealed envelope” method. An allocation table will be generated remotely by the trial statistician at The University of Birmingham to allocate participants in a 1:1 ratio at the level of the individual over the course of the trial. A random number generator will be used to generate a random sequence of the

numbers between 1 to N inclusive. A permuted block randomisation method will be used by randomly selecting blocks of size 2, 4, 6, or 8 in order to maintain balance between the numbers allocated to each of the two groups. The generated table will be uploaded into the REDCap software to be used for participant enrolment. Access to the allocation table will be restricted. Trial staff in Nigeria will not have access to the allocation table. When a participant's details are submitted, the trial arm and a unique study number will be assigned and revealed to the local clinician so that the randomised group that the participant is assigned to cannot be altered.

Participants will be randomised to receive wound dressing treatment with honey twice a week or a normal saline dressing twice a week (control group). The treatment will be applied at the time of twice weekly changes of dressings by local trained nurses or paramedics. These dressing changes are part of routine care and will thus apply to the intervention and control groups. There is no pain from the procedure but dressing changes may take slightly longer for participants in the intervention group. Participants in both groups have twice-weekly dressing changes during their hospital stay until ulcers are healed. Any missed sessions will be noted but this will not be treated as a protocol deviation.

### Intervention Type
Other

### Primary outcome(s)
Assessed from 'blindly' examined photographs:
1. Rate of healing based on one observation per week until the ulcers are healed
2. Time to complete re-epithelisation (up to 84 days)

### Key secondary outcome(s))
Long-term (6-month) end-points, measured using a physical examination of the treatment site:
1. Recurrence of treated ulcer
2. Appearance of a new ulcer
3. Anatomical changes in the limb

Long-term endpoints will be measured using medical records at the time of follow up at 6 months from randomisation:
1. Days hospitalised prior to discharge and total (to include any readmission related to leprosy ulcers) by 6 months
2. Number of visits to any healthcare facility from discharge to the end of follow-up at 6 months

### Completion date
31/12/2024

## Eligibility

### Key inclusion criteria
1. Patients with a chronic foot ulcer of at least 6 weeks duration due to leprosy neuropathy
2. ≥18 years of age
3. Ulcer surface area between 2 and 20 $cm^2$ inclusive
4. Ulcer is clean, dry, and free from infection
5. Patient can provide informed consent

### Participant type(s)
Patient

**Healthy volunteers allowed**
No

**Age group**
Adult

**Lower age limit**
18 years

**Sex**
All

**Total final enrolment**
130

**Key exclusion criteria**
Patients will be excluded if:
1. Ulcer is less than 6 weeks from appearance
2. Less than 18 years of age
3. Ulcer surface area is less than 2 $cm^2$ or more than 20 $cm^2$
4. Ulcer is infected or a diabetic foot ulcer
5. Patient declined to give consent

**Date of first enrolment**
15/02/2022

**Date of final enrolment**
30/06/2024

# Locations

**Countries of recruitment**
Nigeria

**Study participating centre**
**Leprosy Referral Hospital, Chanchaga**
Chanchaga
Minna
Niger State
Minna
Nigeria
-

**Study participating centre**
**St Benedict's TBL and Rehabilitation Hospital**
Ogoja

Nigeria
-

# Sponsor information

**Organisation**
The Leprosy Mission Nigeria

# Funder(s)

**Funder type**
Government

**Funder Name**
National Institute for Health Research

**Alternative Name(s)**
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

# Results and Publications

**Individual participant data (IPD) sharing plan**
The data-sharing plans for the current study are unknown and will be made available at a later date

**IPD sharing plan summary**
Data sharing statement to be made available at a later date

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |

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|---|---|---|---|---|---|
| Protocol file | version 0.6 | 06/10/2021 | 17/11/2021 | No | No |
| Protocol file | version 0.9 | 02/12/2022 | 04/01/2023 | No | No |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |