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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
07/01/2026

Condition category
Infections and Infestations

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

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consequences in terms of loss of function, loss of earnings and stigma, frequently becoming chronically depressed and withdrawn.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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
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
Mixed

Lower age limit
18 years

Upper age limit
100 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

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?
Results article		31/12/2025	07/01/2026	Yes	No
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		11/11/2025	11/11/2025	No	Yes