

Use of honey for the treatment of leprosy ulcer

Submission date 16/11/2021	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 22/12/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 31/12/2024	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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consequences in terms of loss of function, loss of earnings and stigma, frequently becoming chronically depressed and withdrawn.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 cm²)

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
tsakup@tlmnigeria.org

Study website

<https://www.birmingham.ac.uk/research/applied-health/research/nihr-right-leprosy/index.aspx>

Contact information

Type(s)

Scientific

Contact name

Dr Paul Tsaku

ORCID ID

<https://orcid.org/0000-0001-9490-4112>

Contact details

The Leprosy Mission Nigeria
14/16 Kings Drive
Fort Royal Homes Estate
Lugbe
Abuja
Nigeria
000
+234 (0)7035425305
tsakup@tlmnigeria.org

Type(s)

Public

Contact name

Dr Paul Tsaku

Contact details

The Leprosy Mission Nigeria
14/16 Kings Drive
Fort Royal Homes Estate
Lugbe
Abuja
Nigeria
000
+234 (0)7035425305
tsakup@tlmnigeria.org

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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)

Secondary outcome measures

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

Overall study start date

29/08/2021

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 cm² inclusive
4. Ulcer is clean, dry, and free from infection
5. Patient can provide informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

130

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 cm² or more than 20 cm²
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

Sponsor details

14/16 Kings Drive

Fort Royal Homes Estate

Lugbe

Abuja

Nigeria

000

+234 (0)8117918420

office@tlmnigeria.org

Sponsor type

Charity

Website

<https://www.leprosymissionnig.org>

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

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal. Publication of the protocol is also planned.

Intention to publish date

31/12/2024

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?
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