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GoLBeT [Gojjam Lymphoedema Best practice Trial]: a study of the effectiveness of treatment for podoconiosis (non-filarial elephantiasis)

Submission date
16/01/2013

Recruitment status
No longer recruiting

Registration date
24/01/2013

Overall study status
Completed

Last Edited
29/07/2021

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Podoconiosis is one of the forgotten types of leg swelling (elephantiasis) in the tropics. Although an estimated 4 million people are affected by podoconiosis across Africa, there is no government health service provision for patients in countries where it is found. In Ethiopia, where 1 million people with podoconiosis live, non-government organizations (NGOs) have developed simple treatments using low-cost, locally available materials. Treatment includes foot hygiene, skin care, bandaging, exercises to improve lymph drainage and use of socks and shoes. Although the NGOs consider the treatment to be effective, no study has been done to prove that it is. The aim of this study is to test whether the 'standard' treatment reduces the number of times a patient experiences 'acute episodes', when the leg become hot, painful and more swollen than usual. These episodes significantly interfere with patients' ability to work or carry out normal day-to-day tasks. The cost of the treatment will also be measured and information gathered on the economic effects of untreated disease (for example, loss of earnings due to inability to work).

Who can participate?
Men and women who have podoconiosis and are at least 16 years old and who will remain living in the study area for the length of the study

What does the study involve?
Before the study, a survey will be done to collect background information on typical work hours and settings, labour and medical costs and productivity losses related to podoconiosis. We will also do a rapid assessment to identify the best methods of giving information about the study and the approaches to obtaining informed consent preferred by the community. We will allocate 690 podoconiosis patients to one of two groups: either to 'standard' treatment, or to delayed treatment (i.e., 345 patients in each group). Standard treatment will consist of soaking the feet in dilute antiseptic and washing them with soap and water. Moisturising lotion will then be applied to the skin and the feet and lower legs will be bandaged. This will be done every day for one year and patients will attend meetings to learn how to do it. Treatment will be organised through the International Orthodox Christian Charities (IOCC) Podoconiosis Project, which

already has excellent links with the community and local government. The delayed treatment group will receive no treatment for one year, but will receive treatment at the end of the study. The number of acute episodes will be compared between the two groups.

What are the possible benefits and risks of taking part?
Patients allocated to the treatment group will benefit from the treatment they receive for their podoconiosis. Patients allocated to the control arm (delayed treatment) will receive treatment after the study has been completed. Although this means a delay in receiving treatment, only about 3% of patients can access treatment in Ethiopia so most people with podoconiosis receive no treatment at the moment. Possible risks include adverse effects from inexperienced bandaging: this will be mitigated by careful training of project assistants.

Where is the study run from?
The study will be based at the IOCC Debre Markos Podoconiosis Project in East Gojjam Zone, Amhara Region, northern Ethiopia, where podoconiosis is very common. Brighton and Sussex Medical School and the Clinical Trial Facility at the KEMRI-Wellcome Trust Research Programme, Kilifi, Kenya will provide support for the study.

When is the study starting and how long will it run for?
The study will start recruiting from October until December 2013 and the intervention be applied from January 2014 for 1 year.

Who is funding the study?
The study is funded by Medical Research Council (MRC)/UK Department for International Development (DfID)/Wellcome Trust.

Who is the main contact?
Dr Gail Davey, g.davey@bsms.ac.uk
Professor Melanie Newport, m.j.newport@bsms.ac.uk

Study website
http://www.podo.org/research/current/golbet-trial/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Randomised controlled trial of podoconiosis treatment in northern Ethiopia

Acronym
GoLBeT

Study objectives
Golbet means 'be strong' in Amharic.

Standard community-based treatment of podoconiosis lymphoedema improves individual clinical, social and economic outcomes for people with podoconiosis.

Null hypothesis: there will be no difference in outcome between standard and delayed treatment groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Research Governance and Ethics Committee of Brighton & Sussex Medical School, 12/08/2014, ref: 13/107/DAV
2. College of Health Sciences, Addis Ababa University, 12/12/2013, ref: 071/13/SPH
3. Ethiopian Food, Medicine and Health Care Administration and Control Authority, 09/04/2014, ref: 02/6-1/05/39
4. National Research Ethics Review Committee of the Ministries of Health and Science and Technology of Ethiopia, 11/07/2014, ref: 3-1/794/06

Study design
Pragmatic single-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Podoconiosis (non-filarial elephantiasis)

Interventions
Standard podoconiosis lymphoedema management in the community with delayed treatment (as control).

Standard podoconiosis lymphoedema management consisting of twice-weekly group meetings with instruction and practical demonstration of foot hygiene by a community project assistant. Foot hygiene comprises: soaking feet in dilute antiseptic, washing with soap, rinsing with clean water, drying and application of emollient; supervised use of normal or short-stretch bandages for disease stage ≥3; foot elevation and exercises; instruction to practice foot hygiene daily at home; instruction to elevate the foot of the bed or areas slept on; instruction to acquire socks and shoes where possible.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Incidence of acute dermatolymphangioadenitis (ADLA). Mean number of ADLA episodes over 12 months.

Secondary outcome measures
1. Adherence with treatment (foot washing, use of ointment, use of bandages, elevation, exercises, use of socks and shoes)
2. Clinical stage of disease (using scale specifically developed for use in podoconiosis patients)
3. Lower leg and foot circumferences (measured in cm at mid-calf and mid-foot)
4. Presence of mossy changes, wounds and inter-digital entry lesions
5. Duration of ADLA (days)
6. Quality of life (using validated Amharic translation of Dermatology Life Quality Index)
7. Perceived stigma (using recently developed scale for measuring stigma among podoconiosis patients)
8. Economic productivity (days/part-days off work)

Overall study start date
01/12/2013

Completion date
31/05/2017

Eligibility

Key inclusion criteria
1. Patients (male and female) must be at least 16 years old
2. Have a diagnosis of podoconiosis confirmed by the trial team
3. Not be planning to move away from the area during the study period

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
690

Key exclusion criteria
1. Lymphoedema of causes other than podoconiosis
2. History of allergic reaction to treatment materials
3. Mental health disorder affecting ability to adhere to treatment
4. Physical disability beyond that of podoconiosis precluding attendance at group sessions

Date of first enrolment
03/11/2014

Date of final enrolment
15/06/2015

Locations

Countries of recruitment
Ethiopia

Kenya

Study participating centre
International Orthodox Christian Charities
Addis Ababa
Ethiopia
-

Study participating centre
Addis Ababa University
King George VI St
Addis Ababa
Ethiopia
1000

Study participating centre
Kilifi Clinical Trial Facility
Kilifi
Kenya
-

Sponsor information

Organisation
University of Sussex (UK)

Sponsor details
Sussex House
Southern Ring Road
Falmer
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United Kingdom
BN1 9RH

Sponsor type
University/education

Website
http://www.sussex.ac.uk/

ROR
https://ror.org/00ayhx656

Funder(s)

Funder type
Research council

Funder Name
Department for International Development

Alternative Name(s)
Department for International Development, UK, DFID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Wellcome Trust - scheme to fund global health clinical trials (MR/K007211/1)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
A dissemination workshop will be held in May 2017 either in Addis Ababa or in Bahir Dar (the regional capital), depending on security at the time. The primary outcome manuscript will be published by January 2018.

Intention to publish date
01/01/2018

Individual participant data (IPD) sharing plan
The Data Sharing Policy encourages scientists to apply for use of the dataset once a period of a year after the close of the trial has elapsed (during which the trial team will have exclusive use). The datasets are available from Debbie Miller (Global-Health-Research-Administrator@bsms.ac.uk) on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	16/07/2015		Yes	No
Results article	results	01/07/2018		Yes	No
Results article	results	01/12/2018		Yes	No
Other publications	Qualitative assessment of trial	28/07/2021	29/07/2021	Yes	No