

Heat treatment of Buruli ulcer

Submission date 12/08/2008	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 29/08/2008	Overall study status Completed	☐ Protocol
Last Edited 24/02/2009	Condition category Infections and Infestations	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Study information

Scientific Title

Phase change material to treat Buruli ulcer through heat treatment: a prospective observational single centre proof-of-principle study

Study objectives

Buruli ulcer (BU) is a chronic necrotising disease of skin and soft tissue caused by *Mycobacterium ulcerans*. BU has been reported in more than 30 countries, but the major burden lies on children living in remote areas of West Africa associated with swamps and stagnant water bodies.

Heat has been shown to be effective in the treatment of BU in the early 70's. Based on these results, World Health Organization (WHO) guidelines listed the application of heat as a treatment option for BU. However, the heat application devices employed so far were impractical in most endemic countries. We developed a heat delivery device which is easy to apply, rechargeable in hot water, non-toxic and non-hazardous to the environment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from:

1. Ethics Committee of the Medical Faculty Heidelberg (Ethikkommission der Medizinischen Fakultät Heidelberg [Germany]) on the 6th March 2006 (ref: 490/2005)
2. National Ethics Committee (Comite National D'Ethique [Cameroon]) on the 21st August 2006

Primary study design

Observational

Study design

Prospective observational single-centre study (proof-of-principle study)

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Buruli ulcer (BU)

Interventions

Phase change material as heat delivery system as part of a bandage which is applied to the Buruli ulcer and the surrounding tissue of the patient. Due to the properties of the bandage patients can move around freely during treatment.

Duration of heat treatment: 4 weeks (small ulcers and without significant oedema) and 6 weeks (large ulcers and/or significant oedema). Total duration of follow-up: 2 years.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Small ulcers: complete healing (primary closure of ulcer)
2. Large ulcers: healing to a stage that patient can undergo skin grafting
3. Relapse rate over a follow up period of 2 years after completion of heat treatment

Key secondary outcome(s)

Histopathological changes in response to thermotherapy on day 28.

Completion date

27/02/2009

Eligibility

Key inclusion criteria

1. Patients (male and female) aged 6 - 21 years
2. Single ulcer clinically diagnosed as Buruli ulcer (WHO 2001)
3. Laboratory confirmation of Buruli ulcer: on day 0 four swabs from the undermined edges and one diagnostic biopsy from all patients enrolled into the trial on clinical grounds are taken. All samples are investigated by microscopy for acid-fast bacilli (AFB) after Ziehl Neelsen (ZN) staining and by IS2404 real-time polymerase chain reaction (PCR). Histopathological changes typical for BU are recorded.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

Key exclusion criteria

In view of the unproblematic nature of the treatment no relevant adverse effects are foreseen. Nevertheless, patients with significant underlying other communicable and non-communicable diseases are excluded in this first proof-of-principle study.

Date of first enrolment

28/02/2007

Date of final enrolment

27/02/2009

Locations

Countries of recruitment

Cameroon

Germany

Study participating centre

Section of Clinical Tropical Medicine

Heidelberg

Germany

69120

Sponsor information

Organisation

University Hospital Heidelberg (Universitätsklinikum Heidelberg) (Germany)

ROR

<https://ror.org/013czdx64>

Funder(s)

Funder type

Industry

Funder Name

Volkswagen Foundation (VolkswagenStiftung) (Germany) (ref: I/81 308)

Alternative Name(s)

VolkswagenStiftung, The Volkswagen Foundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Germany

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2009		Yes	No