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# Heat treatment of Buruli ulcer

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

**Plain English summary of protocol**
Not provided at time of registration

## 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**

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

## Study design
Prospective observational single-centre study (proof-of-principle study)

## Primary study design
Observational

## Secondary study design
Other

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet

## 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 ulcres 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 measure
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

### Secondary outcome measures
Histopathological changes in response to thermotherapy on day 28.

### Overall study start date
28/02/2007

### 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

### Age group
Not Specified

### Sex
Both

### Target number of participants
10

### 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)

**Sponsor details**
Im Neuenheimer Feld 672
Heidelberg
Germany
69120

**Sponsor type**
Hospital/treatment centre

**Website**
http://www.med.uni-heidelberg.de/

**ROR**
https://ror.org/013czdx64

# Funder(s)

**Funder type**
Industry

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

### Alternative Name(s)
VolkswagenStiftung

### Funding Body Type
Private sector organisation

### Funding Body Subtype
Trusts, charities, foundations (both public and private)

### Location
Germany

## Results and Publications

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

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