

# Efficacy and host-pathogen response of heat treatment in patients with Buruli ulcer (BU) using a Phase Change Material (PCM) device

**Submission date**  
12/02/2009

**Recruitment status**  
No longer recruiting

Prospectively registered

Protocol

**Registration date**  
27/02/2009

**Overall study status**  
Completed

Statistical analysis plan

Results

**Last Edited**  
14/01/2016

**Condition category**  
Infections and Infestations

Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

## Study information

### Scientific Title

A Phase II non-comparative, open label, single-centre study to evaluate the efficacy and host-pathogen response of heat treatment in patients with Buruli ulcer (BU) using a Phase Change Material (PCM) device

## **Acronym**

BU-HEAT-Rx

## **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 and successfully tested in a proof-of-principle-trial (ISRCTN88392614) a heat delivery device which is easy to apply, rechargeable in hot water, non-toxic and non-hazardous to the environment.

Please note that as of 25/11/2009 this trial record has been updated. All updates may be found in the relevant field with the above update date.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

1. Cameroon: National Ethics Committee (Comite National D'Ethique), 30/12/2008
2. Germany: Ethics Committee of the Medical Faculty Heidelberg (Ethikkommission der Medizinischen Fakultät Heidelberg), 28/01/2009, ref: S-424/2008

## **Study design**

Interventional open-label single-arm single-centre trial

## **Primary study design**

Interventional

## **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 BU 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.

Added 25/11/2009:

17 patients have received treatment starting on 20/02/2009 and are now in the follow up period. Along with the original cohort of 17, 5 more cohorts of 16 +/- 2 will be treated over the next 3 years.

## **Intervention Type**

Device

## **Phase**

Phase II

## **Primary outcome(s)**

1. Proportion of patients cured 6 months after completing heat treatment. Cure is defined as complete closure of the wound by epithelialisation or scarification or by skin graft.
2. Proportion of patients recurrence free 12 and 24 months after completing heat treatment

## **Key secondary outcome(s)**

1. Proportion of patients who were not withdrawn for low compliance or who did not withdraw consent after starting the heat treatment
2. Proportion of patients with adverse events (AEs) being at least considered as possibly related to the heat treatment
3. Proportion of patients showing diminishment of bacterial burden in microbiological assessments of punch biopsies and swabs (i.e. reduction of bacterial counts and changes in bacterial morphology in microscopy and in the quantity of *M. ulcerans* DNA/RNA in polymerase chain reaction [PCR]) at day 14 and day 28 (punch biopsies) or days 7, 14 and 28 (swabs) after start of treatment compared to reference samples at day 0
4. Proportion of patients showing qualitatively histopathological signs for infiltration and tissue repair at day 14 and day 28 after start of treatment compared to reference sample at day 0
5. Proportion of patients showing increases in immunological response parameters at day 14 and day 28 after start of treatment compared to reference sample at day 0

## **Completion date**

20/05/2011

## **Eligibility**

### **Key inclusion criteria**

Patients (both males and females, age equal or greater than 4 years) with ulcers clinically diagnosed as BU (WHO 2001)

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Child

### **Lower age limit**

4 years

### **Sex**

All

## **Key exclusion criteria**

1. Patients with significant other communicable and non-communicable diseases:
  - 1.1. Clinical signs and symptoms of significant communicable diseases other than BU (fever, weight loss, night sweats, persistent cough, jaundice, pulmonary or myocardial dysfunction, central nervous system [CNS] involvement, ascites, pleural effusion)
  - 1.2. Clinical signs and symptoms of significant non-communicable diseases (myocardial, pulmonary, renal, CNS)
2. Patients on chemotherapy for BU (streptomycin, rifampicin)

## **Date of first enrolment**

20/02/2009

## **Date of final enrolment**

20/05/2011

## **Locations**

### **Countries of recruitment**

Cameroon

Germany

### **Study participating centre**

**University Hospital Heidelberg**

Heidelberg

Germany

69120

## **Sponsor information**

### **Organisation**

University Hospital Heidelberg (Universitätsklinikum Heidelberg) (Germany)

### **ROR**

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

## **Funder(s)**

### **Funder type**

Other

### **Funder Name**

Volkswagen Foundation (VolkswagenStiftung) (Germany) (ref: I/83 232)

**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?
<a href="#">Results article</a>	results	01/02/2016		Yes	No
<a href="#">Results article</a>	results	01/02/2016		Yes	No