

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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

Secondary study design

Other

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient 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 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 measure

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

Secondary outcome measures

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

Overall study start date

20/02/2009

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

Age group

Child

Lower age limit

4 Years

Sex

Both

Target number of participants

Added 25/11/2009: 100 (6 cohorts of 16 +/- 2)

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)

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

Other

Funder Name

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

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	01/02/2016		Yes	No
Results article	results	01/02/2016		Yes	No