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

Submission date	Recruitment status	[_] Prospectively registered
12/02/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/02/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/01/2016	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

Protocol serial number
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 Fakultaet 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?
Results article	results	01/02/2016		Yes	No
Results article	results	01/02/2016		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes