

## Progress Report: Sri Lanka Clinical Trials Registry

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SLCTR registration number: SLCTR/2023/022

Scientific title of trial: Study to determine the effectiveness, acceptability and feasibility of thermotherapy with radio frequency – induced heat therapy (RFHT) by ThermoMed device for the local/intra lesional treatment of cutaneous leishmaniasis in selected routine clinic settings Sri Lanka.

Date of commencement (enrolment of first participant):

Progression: 6 months /  1 year  2 years  3 years   
At completion

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### 1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: [None](#)

Any changes to trial outcomes after commencement: [None](#)

### 2. Current status

Recruitment status: pending/ recruiting/ recruitment complete: follow up continuing/  
recruitment complete: follow up complete/ recruitment suspended / recruitment  
terminated

Number assessed for eligibility:

Number recruited and allocated/randomized: [36](#)

Number allocated/randomized to each intervention/arm (please edit as relevant):

[Allocated as per treatment decision made by the dermatologists.](#)

Arm 1:

Arm 2:

Losses/exclusions after allocation/randomization (please edit as relevant): [NA](#)

Arm 1:

Arm 2:

### 3. Trial output

Date of trial completion ("last patient, last visit"): [In 2 years](#)

Final sample size: 200

Summary of Interim/Final data (if available):

Patient recruitment started. Treatment has been initiated in 36 cutaneous leishmaniasis patients who are being followed up.

Abstract presentations of results at scientific meetings

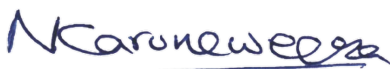
Note: please include a URL link or scanned copy of the abstract [None yet.](#)

Title of Abstract	Full citation (please include authors, date, title of conference and place of presentation, page number of abstract).
NA	

Publications : [None](#)

Note: please include a URL link or scanned copy of the publication

Title of paper	Full citation (please include authors, title of journal, volume, issue and page numbers, and/or DOI)



Prof. Nadira D. Karunaweera

Name and signature of Responsible Registrant/  
Principal Investigator

Date: 1st July 2024