

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The effect of thermal therapy on uremic pruritus and quality of life in patients undergoing hemodialysis

Protocol summary

Summary

objectives: The aim of the study was to identify the effect of thermal therapy with FIR in comparison with non-thermal therapy on uremic pruritus and Assessment of quality of life. Design & setting : A non- randomized, one-blind, controlled trial was performed and the data were collected in 2017. Participants including major eligibility criteria: At least 18 years of age; Ability to communicate in Persian; Diagnosis of uremic pruritus approved by the physician. Exit criterias : Any skin disease; vascular and malignant disorders. Samples size:In each group,20 people and a total of 40 people. The intervention: A system for thermal therapy was used for this study. A quiet and warm room with a far-infrared ray device was used and participants were placed in a supine position on a bed for 15 minutes and kept warm by being wrapped in a blanket. Those in the thermal therapy group were treated with 40C thermal therapy with FIR. A constant temperature of 40C FIR may allow multiple energy transfer into subcutaneous tissue without irritating or overheating the skin.Thermal therapy was performed once a day for 15 minutes on two days a week for a total of 18 sessions. The participants remained on bed rest with the blanket for an additional 30 minutes after the thermal therapy in each session.Control group: The non-thermal therapy group received drug therapy and routine care. The principal investigator stayed with these patients for the same duration as the thermal therapy group.Main outcome measure(variable): uremic pruritus and quality of life in patients undergoing hemodialysis

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041333245N2**

Registration date: **2017-10-17, 1396/07/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-10-17, 1396/07/25

Registrant information

Name

Hamed zare

Name of organization / entity

Shahed university

Country

Iran (Islamic Republic of)

Phone

+98 35 3281 4277

Email address

h.zare@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of Research and Technology of Shahed University;Elderly Research Center of Shahed University

Expected recruitment start date

2017-04-30, 1396/02/10

Expected recruitment end date

2017-07-01, 1396/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of thermal therapy on uremic pruritus and quality of life in patients undergoing hemodialysis

Public title

The effect of thermal therapy on uremic pruritus and quality of life in patients undergoing hemodialysis

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria were: ≥ 18 years of age; able to communicate in persian; a diagnosis of uremia, confirmed in writing by the primary care physician; receiving haemodialysis three times a week for at least three months; having pruritus symptoms; being fully conscious. participants were excluded if they had any dermatological disorders; haematological disorders; organic problems or current use of drugs that might contradict or interfere with the assessments of outcomes; current requirement for haemodialysis more than three times per week due to comorbidity; Individuals who were unable or unwilling to follow the thermal therapy protocol for any reason were excluded from the trial

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahed University

Street address

Shahed University, Facing Imam Khomeini's holy shrine, Persian Gulf Highway, Tehran

City

Tehran

Postal code

3319118651

Approval date

2017-03-05, 1395/12/15

Ethics committee reference number

IR.Shahed.REC.1395.195

Health conditions studied

1

Description of health condition studied

uremic pruritus

ICD-10 code

L80-L99

ICD-10 code description

Other disorders of the skin and subcutaneous tissue

Primary outcomes

1

Description

uremic pruritus

Timepoint

Pre-Test: Before the intervention; Mid-Test: After 1 month from the beginning of the intervention. Post-Test: After two months and 18 sessions of heat therapy.

Method of measurement

location and severity of uremic pruritus assessed by questionnaire and a visual analogue scale (VAS).

Secondary outcomes

1

Description

life quality

Timepoint

Pre-Test: Before the intervention; Mid-Test: After 1 month from the beginning of the intervention. Post-Test: After two months and 18 sessions of heat therapy.

Method of measurement

Assessed by questionnaire (KDQOL- SF) Quality of life for patients with ESRD (Itchy Qol)

2

Description

biochemical indicators

Timepoint

Before thermal therapy 1 (pre-test), and middle thermal therapy 2 (mid-test), After thermal therapy 3 (post-test) months

Method of measurement

Secondary outcome measures included several biochemical indicators

Intervention groups

1

Description

Control group: The non-thermal therapy group received drug therapy and routine care. The principal investigator stayed with these patients for the same duration as the thermal therapy group.

Category

Treatment - Other

2

Description

The intervention: A system for thermal therapy was used for this study. A quiet and warm room with a far-infrared ray device was used and participants were placed in a supine position on a bed for 15 minutes and kept warm by being wrapped in a blanket. Those in the thermal therapy group were treated with 40C thermal therapy with FIR. A constant temperature of 40C FIR may allow multiple energy transfer into subcutaneous tissue without irritating or overheating the skin. Thermal therapy was performed once a day for 15 minutes on two days a week for a total of 18 sessions. The participants remained on bed rest with the blanket for an additional 30 minutes after the thermal therapy in each session.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dialysis ward of shahid sadooghi hospital of yazd

Full name of responsible person

hamed zare

Street address

City

yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research and Technology of Shahed University; Elderly Research Center of Shahed University

Full name of responsible person

Dr.Majideh Heravi karimavi

Street address

Shahed University, Facing Imam Khomeini's holy shrine, Persian Gulf Highway, Tehran

City

tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Deputy of Research and Technology of Shahed University; Elderly Research Center of Shahed University

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

shahed university

Full name of responsible person

Hamedzare

Position

Master of intensive care

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Hamed Zare

Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty