

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Effect of massage with ostrich oil versus placebo on the severity of itching and quality of life in hemodialysis patients: a single-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of massage with ostrich oil versus placebo on the severity of itching and quality of life in hemodialysis patients

Design

This is a single-blind randomized clinical trial, phase II, in which 70 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible hemodialysis patients who will refer to Shahid Beheshti Hospital during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 65 years; History of hemodialysis for at least 6 months; Alternating itching of the skin in day and night; Exclusion criteria: Open or infectious wound or cellulite; Vascular thrombosis; Seizure; Paralysis of the limbs; Using pacemaker; History of allergic reactions

Intervention groups

Intervention group: Massage of the location of skin itching with 1 ml ostrich oil at 10 to 15 °C for 10 minutes every night for one month Control group: Massage of the location of skin itching with 1 ml placebo oil at 10 to 15 °C for 10 minutes every night for one month

Main outcome variables

Primary outcome: Assessing itching of the skin, Assessing quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N237**

Registration date: **2018-09-27, 1397/07/05**

Registration timing: **prospective**

Last update: **2018-09-27, 1397/07/05**

Update count: **0**

Registration date

2018-09-27, 1397/07/05

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-02, 1397/07/10

Expected recruitment end date

2019-03-01, 1397/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of massage with ostrich oil versus placebo on the severity of itching and quality of life in hemodialysis patients: a single-blind randomized clinical trial

Public title

Effect of massage with ostrich oil versus placebo on the

severity of itching and quality of life in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 65 years History of hemodialysis for at least 6 months Alternating itching of the skin in day and night

Exclusion criteria:

Open or infectious wound or cellulite Vascular thrombosis Seizure Paralysis of the limbs Using pacemaker History of allergic reactions

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through drawing of lots

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients will be unaware of the type of intervention. Therefore, the trial will be run as single-blind

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2018-09-01, 1397/06/10

Ethics committee reference number

IR.UMSHA.REC.1397.407

Health conditions studied

1

Description of health condition studied

Itching

ICD-10 code

L29.9

ICD-10 code description

Pruritus, unspecified

Primary outcomes

1

Description

Assessing itching of the skin

Timepoint

Every week after intervention for 4 weeks

Method of measurement

By history taking

2

Description

Assessing quality of life

Timepoint

One month after intervention

Method of measurement

Using the standard quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Massage of the location of skin itching with 1 ml ostrich oil at 10 to 15 °C for 10 minutes every night for one month

Category

Treatment - Drugs

2

Description

Control group: Massage of the location of skin itching with 1 ml placebo oil at 10 to 15 °C for 10 minutes every night for one month

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Zahra Sadeghi Nejad

Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Hamedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Zahra Sadeghi Nejad

Position

Nursing Student

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Arezoo Karampourian

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Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available