

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Compare the effect of topical application of rosemary and menthol on musculoskeletal pain in hemodialysis patients

Protocol summary

Summary

The present study was conducted with the aim to determine and compare the effects of topical application of menthol and rosemary on musculoskeletal pain in hemodialysis patients. The present single-blind clinical trial recruited 105 eligible patients undergoing hemodialysis in selected hospitals affiliated to Isfahan University of Medical Sciences selected by convenient sampling. Inclusion criteria is include: , Age between 18-65 years, hemodialysis three times a week, Not addiction, 3 months after initiation of dialysis, severity of Pain in the lower extremities at least 4, Non-transplant candidates during the study, Full alert, Having the ability to communicate verbally, Not having legs vascular access, No injury to the skin at the site of drug use. Exclusion criteria include: the patients who do not like to continue to participate in the study, hospitalization during the study. The samples were divided randomly using random numbers table into three groups: consumer rosemary, menthol and placebo. Participants' severity of pain recorded prior to intervention in the questionnaire. All three groups applied medication on the site of pain in their legs three times a day for three days and recorded the severity of pain four hours after morning and afternoon applications . Mean pain severity during three days of intervention was considered as the severity of pain after intervention. Data were collected using a demographic and disease questionnaire and numeric rating scale for Pain, we investigated the effectiveness of these two drugs on pain patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016101430296N1**

Registration date: **2016-10-30, 1395/08/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-10-30, 1395/08/09

Registrant information

Name

Sekine Keshavarzian Kelishadi

Name of organization / entity

Isfahan University Of Medical Sciences

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Iran (Islamic Republic of)

Phone

+98 31 3748 2010

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s.keshavarzian@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vince Chancellor for Research, Isfahan University Of Medical Sciences

Expected recruitment start date

2016-04-08, 1395/01/20

Expected recruitment end date

2016-05-19, 1395/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effect of topical application of rosemary and menthol on musculoskeletal pain in hemodialysis patients

Public title

the effect of topical application of rosemary and menthol on musculoskeletal pain in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

They have constant and active file in hemodialysis ward, Age between 18-65 years, There was no known history of muscle diseases, Were fully alert, During the study weren't transplant candidates, Not addiction, There was no injury to the skin Such as skin rashes or ulcers at the site of drug, Not having legs vascular access, Having the ability to communicate verbally, They passed at least 3 months of starting dialysis, Hemodialysis three times a week, Were literate And reported pain severity was at least four in the lower extremities. Exclusion criteria: the patients who do not like to continue to participate in the study, Hospitalization during the study

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University Of Medical Sciences

Street address

Hezar Jerib Avenue, Isfahan, Iran

City

Isfahan

Postal code

8147673461

Approval date

2016-02-09, 1394/11/20

Ethics committee reference number

IR.mui.rec.394968

Health conditions studied

1

Description of health condition studied

Hemodialysis patients

ICD-10 code

N19

ICD-10 code description

Unspecified kidney failure

2

Description of health condition studied

HEMODIALYSIS PATIENT

ICD-10 code

N17

ICD-10 code description

Acute renal failure

Primary outcomes

1

Description

pain severity

Timepoint

Before intervention and 4 hours after taking the medication in the morning and afternoon during the study

Method of measurement

numeric rating scale for Pain

Secondary outcomes

empty

Intervention groups

1

Description

During the three day study, subjects in the intervention group with Menthol, Menthol Drops 5% used 10 drops topically three times a day at the site of the pain

Category

Treatment - Drugs

2

Description

During the three day study, subjects in the intervention group with rosemary used rosemary spray (containing 1 and 8 Cineole, kanazol) 2 puffs topically three times a day at the site of the pain

Category

Treatment - Drugs

3

Description

During the three day study, subjects in the placebo

treatment group used Vaseline 1 Ablykatvr topically
three times a day at the site of the pain

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

khoshid Hospital

Full name of responsible person

sekine keshavarziankelishadi

Street address

ostandari avenue, Isfahan, Iran

City

Isfahan

2

Recruitment center

Name of recruitment center

Emam Khomeini falavarjan Hospital

Full name of responsible person

sekine keshavarzian kelishadi

Street address

Basig Boulevard ,falavarjan ,isfahan

City

Isfahan

3

Recruitment center

Name of recruitment center

Amin Hospital

Full name of responsible person

sekine keshavarzian kelishadi

Street address

Ebne sina avenue, Isfahan, Iran

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vince Chancellor for Research, Isfahan University Of
Medical Sciences

Full name of responsible person

Dr Mahdi Nematbakhsh PhD in physiology

Street address

Hezar jrib Avenue, Isfahan University Of Medical
Sciences

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vince Chancellor for Research, Isfahan University Of
Medical Sciences

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

Isfahan University Of Medical Science, Faculty Of
Nursing and Midwifery

Full name of responsible person

Nahid Shahgholian

Position

Msc of nursing, Department of special care, Member of
nursing and midwifery care research center,

Other areas of specialty/work

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Position

Bachelor of nursing (Msc student of nursing)

Other areas of specialty/work

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Position

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Other areas of specialty/work**Street address**

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Postal code**Phone****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