Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

clinical trial comparison effect of rosemary and placebo on decreasing pain of acute law back patients

Protocol summary

Summary

This research is a clinical trial that will be done in order to analyze the analogous analgesic effects of rosemary ointment and placebo in patients with acute law back pain who will be hospitalized before surgery. Participants of the study will be whole patients with acute law back pain who come to the hospital. Sampling method includes patients who are not allergic to rosemary ointment and do not have any skin deficiency on their waist as well, twenty- four hours before the surgery.They also should be males and willing in order to participate in the study. The patients will be chosen randomly along with single blind method and then they will included in one of the experimental(48 people) and control(48) groups by chance respectively. In order to decrease the intervention factors the patients will be chosen homogeneously so that they will benefit all the cures evenly. At first the rate of the pain of the patients who are included in the experimental group will be measured by VAS and then they will be recorded. Next the rosemary ointment for the patients of this group is rubbed on their waist in the size of twenty centimeters to twenty centimeters with the thickness of one tenth in centimeter in a circular smooth massage for five minutes from center towards outside locally and then the rate of their pain will be measured and recorded every thirty minutes again for sixth times in total. In the control group the pain of the patients will be measured and recorded Simultaneously before intervention, then Vaseline (the placebo) is rubbed on their waist in the size of twenty centimeters to twenty centimeters with the thickness of one tenth in centimeter in a circular smooth massage for five minutes from center towards outside locally and then the rate of their pain will be measured and recorded every thirty minutes again for sixth times in total. At last, the rate of pain will be compared in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017060434328N1**
Registration date: **2017-09-14, 1396/06/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-09-14, 1396/06/23

Registrant information

Name
Ruhollah Mahdiun
Name of organization / entity
Hamedan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Researcher

Expected recruitment start date

2017-08-28, 1396/06/06

Expected recruitment end date

2017-09-28, 1396/07/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
clinical trial comparison effect of rosemary and placebo on decreasing pain of acute law back patients

Public title
The effect of Rosemary in decreasing of pain in patients with backache

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: patients who have acute backache and do not have any information about the effects of rosemary; become fully conscious and be able to analyze pain based on Visual Analog Scale(VAS) and do not have any skin deficiency in pain place as well; patients who are males. Exclusion criteria: patients who experience consciousness reduction during the research; disinclination of chosen patient about cooperation with the researcher; patient's allergy to rosemary ointment.

Age
No age limit

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **96**

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
Hamedan University of Medical Sciences

Street address
Hamedan University of Medical Sciences, across from Mellat park, after Pajohesh sq.

City
Hamedan

Postal code
6565165131

Approval date
2017-05-02, 1396/02/12

Ethics committee reference number
IR.UMSHA.REC.1396.85

Health conditions studied

1

Description of health condition studied
Back ache

ICD-10 code
M54.5 Low

ICD-10 code description
Acute low back pain diseases

Primary outcomes

1

Description
Low back pain patients

Timepoint
Before the intervention and after the intervention for 6 times at an interval of every half an hour

Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Sampling method includes patients who are not allergic to rosemary ointment and do not have any skin deficiency on their waist as well, twenty- four hours before the surgery.They also should be males and willing in order to participate in the study. The patients will be chosen randomly along with single blind method and then they will included in the experimental group by chance respectively. In order to decrease the intervention factors the patients will be chosen homogeneously so that they will benefit all the cures evenly.At first the pain of the patients in the experimental group will be measured and recorded by VAS, then the rosemary ointment for the patients of this group is rubbed on their waist in the size of twenty centimeters to twenty centimeters with the thickness of one tenth in centimeter in a circular smooth massage for five minutes from center towards outside locally and then the rate of their pain will be measured and recorded every thirty minutes again for sixth times in total.

Category
Treatment - Drugs

2

Description
In the control group first the pain of the patients will be measured and recorded by VAS Simultaneously, then (Vaseline) the placebo is rubbed on their waist in the size

of twenty centimeters to twenty centimeters with the thickness of one tenth in centimeter in a circular smooth massage for five minutes from center towards outside locally and then the rate of their pain will be measured and recorded every thirty minutes again for sixth times in total.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat technichal and super technichal training, treatment hospital
Full name of responsible person
Ruhollah Mahdiun
Street address
Hamedan Besat hospital, Mazdaghineh road, Motahhari Blvd, Resalat sq. Hamedan
City
Hamedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Ruhollah Mahdiun
Street address
Mobasher Kashani dormitary, Mahdiyeh ST., Hamedan
City
Hamedan
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
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
Hamedan University of Medical Sciences
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Ruhollah Mahdiun
Position
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Other areas of specialty/work
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Person responsible for scientific inquiries

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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