Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The comparison of local camomille product oil and sesame oil on nurses chronic low back pain

Protocol summary

Study aim
The comparison of local camomille product oil and sesame oil on employed nurses chronic low back pain at hospital.

Design
randomized double- blind clinical trial

Settings and conduct
At the first intervention group, by the researcher, anointment with the camomille oil and without deep massage will be used on the back and at the place of the pain. Also at the second intervention group, anointment with sesame oil on the back wil be used and by the researcher massage is given gentley with the palm. At the each group, the duration of the intervention will be 3 weeks, twice a day. For men, scholar help will be used. Rajaee and Ghaem hospitals at Alborz will be the location of the study.

Participants/Inclusion and exclusion criteria
nursing grades , 25 to 60 years old; not having spondylosis, lordosis, kyphosis, scoliosis, scoliosis; not having malignancy in spine; nursing with chronic pain in back more than 12 weeks; not using analgesic drugs regularly; not using analgesic oils regularly; nursing that are not under treated with medications, physiotherapy, reformative exercises, hydrotherapy; no history of spine surgery. Major exclusion criteria: unwillingness in participating at study; not participating at study more than 2 days; pregnancy.

Intervention groups
first intervetion(anointment with camomille product oil) and second intervention(anointment with sesame oil)

Main outcome variables
pain intensity will be that before the intervention and at the end of the first, second, third and fourth week will be assessed.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170812035634N1**
Registration date: **2018-01-08, 1396/10/18**
Registration timing: **retrospective**

Last update: **2018-01-08, 1396/10/18**
Update count: **0**

Registration date
2018-01-08, 1396/10/18

Registrant information

Name
Mina Abolfazlie

Name of organization / entity
Faculty of Nursing and Midwifery,Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Tehran university of medical sciences faculty of nursing and midwifery

Expected recruitment start date
2017-09-11, 1396/06/20

Expected recruitment end date
2017-12-11, 1396/09/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The comparison of local camomille product oil and sesame oil on nurses chronic low back pain

Public title
The comparison of local camomille product oil and sesame oil on nurses chronic low back pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
nursing grades , 25 to 60 years old; not having spondylosis, lordosis, kyphosis, scoliosis; not having malignancy in spine; nursing with chronic pain in back more than 12 weeks; not using analgesic drugs regularly; not using analgesic oils regularly; nursing that are not under treated with medications, physiotherapy, reformative exercises, hydrotherapy; no history of spine surgery.

Exclusion criteria:
unwillingness in participating at study; not participating at study more than 2 days; pregnancy.

Age
From **25 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **74**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples will be selected by simple random sampling method from all wards of the hospital and will be divided to two groups as the first and second intervention groups. Then the design of permutation blocks will be done. That way, A letter for the first group intervention and B letter for the second group intervention will be considered. AB, for digits from 0 to 4, and BA from digits from 5 to 9 will be considered. According to sortition, if the first person will be from 0 to 4 digits will stand in the first intervention group and the next person will be in the second group intervention. If the first person will be from 5 to 9 digits will stand in the second group and the next person wil be in the first group intervention. Thus, sortition will be done for 74 samples by 37 times.

Blinding (investigator's opinion)
Double blinded

Blinding description
The researcher and the samples will not know the content of the oils and also the basis of the two oils will be the same, as the result those are similar in the appearance, smell and color.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethicsl Commitee of Tehran Faculty of Nursing and Midwifery and rehabilitation

Street address
Faculty of Nursing and Midwifery, Nosrat Sharghi Street, Tohid Square, Tehran

City
Tehran

Province
Tehran

Postal code
1419733171

Approval date
2017-01-03, 1395/10/14

Ethics committee reference number
IR.TUMS.FNM.REC.1395.1396

Health conditions studied

1

Description of health condition studied
low back pain

ICD-10 code
m00-m99

ICD-10 code description
Diseases of the musculoskeletal system and connective tissue

Primary outcomes

1

Description
Treatment Satisfaction

Timepoint
After Intervention

Method of measurement
Global scale of relieve pain satisfaction

2

Description
Absenteeism

Timepoint
Two months before intervention, Two months after intervention

Method of measurement
Questionnaire

3

Description
Pain
Timepoint
Before Intervention, At the end of the first, Second, Third week, One week after intervention
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
At the first intervention group, camomille product oil will be used in the area where pain occurs for 3 weeks twice a day. By the way that the oil is placed on the skin surface with the palm and without the deep pressure and the oil cover the intended are
Category
Treatment - Drugs

2

Description
The sesame oil will be used for the second intervention group, By the way that the sesame oil will be placed at the back and the area that there is pain and the arounds with the palm, without deep massage. The minimum amount of the oil that will be used i
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem hospital
Full name of responsible person
Mina abolfazlie
Street address
Dolatabad Intersection, Karaj, Alborz
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2

Recruitment center
Name of recruitment center
Rajaee Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Masood Younesian
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Central building of Tehran University of Medical Sciences, Qhds street, Keshavarz Blvd
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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
Tehran 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

Tehran University of Medical Sciences

Full name of responsible person
Mina abolfazlie ghamsari

Position
Master of Nursing

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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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