Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of aromatherapy massage with lavender and ginger essential oil on pain,Joint stiffness and physical function in patients with knee osteoarthritis

Protocol summary

Study aim
Determining the effect of aromatherapy massage with lavender and ginger essential oil on pain, joint dryness and physical function in patients with knee osteoarthritis

Design
Clinical examination work with control group, with parallel, randomized group 2 phases on 120 patients

Settings and conduct
After visiting the rheumatology clinic and random selection, patients were divided into 4 groups, two intervention groups, each containing lavender3% oil and ginger3%, and the placebo group sesame oil and the control group did not receive any medication. Only the interventionist and the analyst were unaware of the groups studied

Participants/Inclusion and exclusion criteria
1=Lack of treatment with injectable steroids and physiotherapy 2=Take the same medication as your doctor advised to relieve pain 3=Written personal consent 4=. Approval of primary knee osteoarthritis by a rheumatologist 5=Knee surgery during the study 6=Lack of willingness to continue participating in the study

Intervention groups
Patients in lavender, ginger, and sesame groups were given essential oils, but patients in the control group did not receive any essential oil.

Main outcome variables
Using the results of this research and if the therapeutic effects of ginger oil are proven and compared with lavender, it can be used in better treatment with less pain, joint dryness and quality of physical performance of patients with knee osteoarthritis.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200314046772N1**
Registration date: **2020-06-22, 1399/04/02**
Registration timing: **retrospective**

Last update: **2020-06-22, 1399/04/02**
Update count: **0**

Registration date
2020-06-22, 1399/04/02

Registrant information

Name
iran hayati

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 58 3726 3253

Email address
hayatisomayeh1372@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-22, 1398/10/01

Expected recruitment end date
2020-03-20, 1399/01/01

Actual recruitment start date
2019-12-22, 1398/10/01

Actual recruitment end date
2020-03-15, 1398/12/25

Trial completion date
2020-03-15, 1398/12/25

Scientific title
Comparison of the effect of aromatherapy massage with lavender and ginger essential oil on pain,Joint stiffness

and physical function in patients with knee osteoarthritis

Public title
Comparison of the effect of aromatherapy massage with lavender and ginger essential oil on pain,Joint stiffness and physical function in patients with knee osteoarthritis

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
1. Approval of primary knee osteoarthritis by a rheumatologist Be able to understand the explanations and complete the interview Written personal consent Age 25-75 years Lack of cancer, pregnancy and coagulation disorders such as hemophilia, asthma (steroid use) Lack of treatment with injectable steroids and physiotherapy No ulcers above the knee joint The duration of the disease is at least 2 years No odor problem Lack of food and drug sensitivity and intolerance Take the same medication as your doctor advised to relieve pain No history of knee joint surgery No symptoms of acute infection at the knee joint Do not take any drugs (no addiction)

Exclusion criteria:
Knee surgery during the study Prescribe physiotherapy for knee pain during the study Allergic reactions to ginger and lavender during the study Lack of willingness to continue participating in the study Increased pain intensity and uncontrollability with prescription drugs Occurrence of any health problem that, at the discretion of the physician in question, is a continuation of the intervention to the detriment of the sample Hospitalization for any reason Do not take the drug more than once a week Take any drugs Oral ginger and lavender

Age
From **25 years** old to **75 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **140**
Actual sample size reached: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
After obtaining written consent from the patients, those who have the conditions to enter the intervention should randomly select the card from the bag mentioned on the intervention groups and in one of the studied groups (ginger, lavender، Sesame and control)

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Birjand University of Medical Sciences Ethics Committee

Street address
Ghaffari Street 21

City
birjand

Province
South Khorasan

Postal code
۹۷۱۷۸۵۳۵۷۷

Approval date
2019-11-30, 1398/09/09

Ethics committee reference number
IR.BUMS.REC.1398.269

Health conditions studied

1

Description of health condition studied
Knee osteoarthritis

ICD-10 code
M17

ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
Pain score in WOMAC questionnaire

Timepoint
Before intervention، Immediately after the intervention،2 weeks after the intervention، 4 weeks after the intervention

Method of measurement
womac questionnaire

2

Description
stiffness Joint score in WOMAC questionnaire.

Timepoint
Before intervention، Immediately after the intervention،2 weeks after the intervention، 4 weeks after the intervention

Method of measurement
womac questionnaire

3

Description
Physical performance score in the WOMAC questionnaire
Timepoint
Before intervention، Immediately after the intervention،2 weeks after the intervention، 4 weeks after the intervention
Method of measurement
womac questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
groups involved(1)، lavender 3% prepared by Noshad factory and they were asked to massage the oil on their knees once a day for 4 weeks and 20 minutes each time in a relaxed state.
Category
Rehabilitation

2

Description
groups involved(2)، involved ginger 3% made prepared by Noshad factory and they were asked to massage the oil on their knees once a day for 4 weeks and 20 minutes each time in a relaxed state.
Category
Rehabilitation

3

Description
groups involved(3)،The placebo group was given 50 cc of sesame oil prepared by Noshad factory and they were asked to massage the oil on their knees once a day for 4 weeks and 20 minutes each time in a relaxed state.
Category
Placebo

4

Description
Control group: This group of patients performed only routine care
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Birjand Health Centers
Full name of responsible person
Ahmad Nasiri Forg
Street address
Ghaffari Street 21
City
birjand
Province
South Khorasan
Postal code
9717853577
Phone
+98 56 3238 1427
Email
hayatisomayeh1372@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Tooba Kazemi
Street address
GHaffari Street 21
City
Birjand
Province
South Khorasan
Postal code
۹۷۱۷۸۵۳۵۷۷
Phone
+98 56 3244 0388
Fax
+98 56 3244 0388
Email
drtooba.kazemi@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Birjand University of Medical Sciences
Proportion provided by this source
90
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
Birjand University of Medical Sciences
Full name of responsible person

Somayeh Hayati
Position
Master's degree in nursing (medical-surgical)
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
GHaffari Street 21
City
Birjand
Province
South Khorasan
Postal code
۹۷۱۷۸۵۳۵۷۷
Phone
+98 930 044 2934
Email
hayatisomayeh1372@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Ahmad Nasiri Forg
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
GHaffari Street 21
City
Birjand
Province
South Khorasan
Postal code
۹۷۱۷۸۵۳۵۷۷
Phone
+98 915 163 7519
Email
Nasiri2006@bums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Somayeh Hayati
Position
Master's degree in nursing (medical-surgical)
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
GHaffari Street 21
City
Birjand
Province
South Khorasan
Postal code
۹۷۱۷۸۵۳۵۷۷
Phone
+98 930 044 2934
Email
hayatisomayeh1372@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Information about the main consequence or the like can be shared.
When the data will become available and for how long
Start the access period from 1400 and after printing the results
To whom data/document is available
In case of further study in this field and related studies
Under which criteria data/document could be used
In case of further study in this field and related studies
From where data/document is obtainable
Birjand University of Medical Sciences, Central Library
What processes are involved for a request to access data/document
It must be pursued through the university
Comments