Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of chamomile oil on the severity of nonspecific low back pain in pre-hospital emergency staff

Protocol summary

Study aim
To determine the effect of chamomile oil on the severity of non-specific low back pain in pre-hospital emergency operation staff

Design
In Clinical Trial, by using block randomization, the 90 Patients enter in intervention, placebo, or control group. Parallel groups, double blind.

Settings and conduct
This study is done in Gilan. The intervention group will receive chamomile oil and placebo group, paraffin. The control group does not receive intervention. Intervention and placebo groups and statistics specialist are blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Pre-hospital Emergency Operations Staff; Male gender; Age 25 to 55 years old; Confirming the non-specificity of low back pain by a neurologist; Low back pain severity with a minimum score of 4 out of 10. Exclusion criteria: Congenital Disorders; Skin disorders in the waist; A history of musculoskeletal disorders; History of waist and spinal cord trauma; Taking steroids; Narcotic use; Analgesic consumption; Malignant diseases; Infectious diseases; Osteoporosis; Leave or sick leave at the time of the intervention.

Intervention groups
The intervention group in the waist area of 100 cm^2 uses 1.5 cc of chamomile oil with a plastic applicator three times a day (morning, noon, and night) for three weeks. The placebo group in the waist area of 100 cm^2 uses 1.5 cc of paraffin oil with a plastic applicator three times a day (morning, noon, and night) for three weeks. The control group does not receive intervention.

Main outcome variables
The severity of back pain and the degree of interference in daily routine are assessed by a brief pain questionnaire, at the beginning of the study; and then weekly; and at the end of the treatment.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110427006318N11**
Registration date: **2019-03-03, 1397/12/12**
Registration timing: **prospective**

Last update: **2019-03-03, 1397/12/12**
Update count: **0**

Registration date
2019-03-03, 1397/12/12

Registrant information

Name
Monir Nobahar

Name of organization / entity
Semnan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 23 3365 4190

Email address
Nobahar43@Yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-09, 1398/01/20

Expected recruitment end date
2019-10-12, 1398/07/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of chamomile oil on the severity of nonspecific low back pain in pre-hospital emergency staff

Public title
The effect of chamomile oil on the severity of low back pain in pre-hospital emergency staff
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Pre-hospital Emergency Operations Staff Male gender Age 25 to 55 years old Confirming the non-specificity of low back pain by a neurologist Low back pain severity with a minimum score of 4 out of 10
Exclusion criteria:
Congenital Disorders Skin disorders in the waist A history of musculoskeletal disorders History of waist and spinal cord trauma Taking steroids Narcotic use Analgesic consumption Malignant diseases Infectious diseases Osteoporosis Leave or sick leave at the time of the intervention
Age
From **25 years** old to **55 years** old
Gender
Male

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to establish the number of samples assigned to each group (intervention, placebo and control), a random method with 6 blocks is used, so that each block has an equal number of each group, and the research sample assigned to the groups of the study by blocks randomization
Blinding (investigator's opinion)
Double blinded
Blinding description
Intervention groups and placebo are unaware of the nature of the oil. The statistics specialist is not aware of the assignment of individuals to groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Semnan University of Medical sciences
Street address
Semnan University of Medical Sciences, Basij Boulevard, Semnan
City
Semnan
Province
Semnan
Postal code
3513138111
Approval date
2019-02-19, 1397/11/30
Ethics committee reference number
IR.Semums.Rec.1397.271

Health conditions studied

1

Description of health condition studied
low back pain
ICD-10 code
M70.9
ICD-10 code description
Unspecified soft tissue disorder related to use, overuse and pressure

Primary outcomes

1

Description
The severity of back pain and the degree of interference in daily routine are assessed by a brief pain questionnaire.
Timepoint
A short questionnaire of pain is evaluated at the beginning of the study, then on a weekly and at the end of the treatment.
Method of measurement
Brief pain questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group in the waist area of 100 cm^2 uses 1.5 cc of chamomile oil with a plastic applicator three times a day (morning, noon, and night) for three weeks.
Category
Other

2

Description
Intervention group: The placebo group in the waist area of 100 cm² uses 1.5 cc of paraffin oil with a plastic applicator three times a day (morning, noon, and night) for three weeks.

Category
Placebo

3

Description
Control group: The control group does not receive intervention.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
This study is done in the pre-hospital emergency department of Gilan.

Full name of responsible person
Monir Nobahar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Dr Parviz Kokhaei

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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
Semnan 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
Semnan University of Medical Sciences

Full name of responsible person
Monir Nobahar

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Data is confidential
Study Protocol
Yes - There is 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
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Data is confidential
When the data will become available and for how long
It was possible to publish the paper from the study.
To whom data/document is available
Research group
Under which criteria data/document could be used
After publishing the resulting paper, it can be made available to others in order to use the results of the study.
From where data/document is obtainable
An article published in an valid journal among available journals
What processes are involved for a request to access data/document
The process of publishing an article in the journal
Comments