Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of Basil (Ocimum basilicum L.) Oil on Severity of Low back pain of patients after coronary angioplasty

Protocol summary

Study aim

Determining the effect of basil oil on the severity of low back pain in patients after coronary artery angioplasty

Design

The third phase of the clinical trial with a control group with parallel group design, which will be implemented by random allocation method with blocks classified by sex and age (25 to 44 years and 45 to 64 years) with the 64 sample.

Settings and conduct

This study will be performed in the angioplasty department of Al-Zahra Hospital in Sari city.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Non-emergency angioplasty candidate through femoral, Age between 25 and 64 years, Body mass index between 25-29/9, No known previous history of skin allergies, Lack of low back pain before angioplasty, Get a pain score of at least 3 after three hours of angioplasty with visual Analogue Scale Exclusion criteria:Receiving analgesic for any reason during the intervention,Occurrence of active hemorrhage during angioplasty

Intervention groups

Intervention group: A number of patients eligible to enter the study. Control group: A number of patients eligible to enter the study equal to the intervention group, which will be determined based on the Pilot study. The intervention, involves the use of two milliliters of the Basil oil made by Arterina company, will be poured to the 10 by 10 centimeter sterile gas and fix to the lumbar region with a glue. For the control group, two milliliters of Lubricant gel, is poured on a piece of 10 by 10 centimeter sterile gauze and fix to the lumbar region with a glue.

Main outcome variables

Low back pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140721018550N9**
Registration date: **2020-05-10, 1399/02/21**
Registration timing: **prospective**

Last update: **2020-05-10, 1399/02/21**
Update count: **0**

Registration date

2020-05-10, 1399/02/21

Registrant information

Name

Nayyereh Raiesdana

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 23 3345 3867

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nr_dana@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-10-22, 1399/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of Basil (Ocimum basilicum L.) Oil on Severity of Low back pain of patients after coronary angioplasty

Public title
The effect of Basil Oil on Severity of Low back pain

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Non-emergency angioplasty candidate through femoral Age between 25 and 64 years Body mass index between 25-29/9 No known previous history of skin allergies Lack of low back pain before angioplasty Get a Low back pain score of at least 3 after three hours of angioplasty with visual Analogue Scale

Exclusion criteria:
Receive analgesic for any reason during the intervention Occurrence of active hemorrhage during angioplasty

Age
From **25 years** old to **64 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
We first assign four subgroups (stratum): 1 - Women 25 to 44 years 2 - Men 25 to 44 years 3 - Women 45 to 64 years 4 - Men 45 to 64 years old Each patient enrolled in the study is placed in one of these four groups. Then, using the randomized random list for each stratum (4 predefined lists), that person is in the intervention group A or control B. To create the desired list of 6 possible blocks, we assign quadrants to each numerical block (from I to VI): According to the random numbers table, numbers 1 through 6 correspond to the above blocks and do not count numbers 7 to 9 and 0. Random numbers are generated with Excel. Then the assignment list (from left to right) is determined for each stratum.

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
Ethics Committee of Semnan University of Medical Sciences

Street address
Nursing and Midwifery colledge, Semnan University of Medical Sciences, Kilometer5 Damghan road, Semnan, Iran

City
Semnan

Province
Semnan

Postal code
3513138111

Approval date
2020-03-10, 1398/12/20

Ethics committee reference number
IR.SEMUMS.REC.1399.012

Health conditions studied

1

Description of health condition studied
Low back pain after Coronary angioplasty

ICD-10 code
M54.5

ICD-10 code description
Low back Pain

Primary outcomes

1

Description
Low back pain

Timepoint
Three hour after angioplasty and 3 and 6 hour after intervention

Method of measurement
Visual analogue Scale(VAS)

Secondary outcomes

1

Description
Blood pressure

Timepoint
Three hours after angioplasty and three and six hour after intervention

Method of measurement
Digital Sphygmomanometer

2

Description
Pulse Rate

Timepoint
Three hours after angioplasty and three and six hour

after intervention

Method of measurement

Saadat Monitoring

Intervention groups

1

Description

Intervention group:At first, the demographic information questionnaire is completed and then the low back pain is measured with a pain visual analogue scale, and their blood pressure and pulse rate are measured and recorded with the same digital device in the supine position.After that, two milliliters of basil oil is poured on a piece of gas and glued with a wicker glue in the lumbar region. Then, at intervals of 3 and 6 hours after the intervention, the severity of low back pain is measured with a pain visual analogue scale and blood pressure and pulse rate in both stages from the same arm and in the supine position measured and recorded.

Category

Other

2

Description

Control group:At first, the demographic information questionnaire is completed and then the low back pain is measured with a pain visual analogue scale, and their blood pressure and pulse rate are measured and recorded with the same digital device in the supine position. After that, two milliliters of lubricant gel is poured on a piece of gas and glued with a wicker glue in the lumbar region. Then, at intervals of 3 and 6 hours after the intervention, the severity of low back pain is measured with a pain visual analogue scale and blood pressure and pulse rate in both stages from the same arm and in the supine position measured and recorded.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemeh Al-Zahra hospital affiliated to Mazandaran University of Medical sciences

Full name of responsible person

Dr. Abol ghasem Falah

Street address

Iran,Mazandaran,Sari, Artesh Bolevard, Fatemeh Al-Zahra hospital

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Parviz Kokhaei

Street address

Semnan -Semnan University of Medical Sciences-Deputy Minister for Research and Technology

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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

Nayyereh Raiesdana

Position

Faculty memeber(Assisstant professor)

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Position
Faculty member(Assisstant professor)

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Other areas of specialty/work
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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
There is no additional data.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not 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
Not applicable

Data Dictionary
Not applicable