Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

A Clinical Trial to Compare the Effects of Oral Tarooneh and Placebo on Patients' Pain after Lumbar surgery

Protocol summary

Summary

Objective: The goal of this study is to determine the effect of oral Tarooneh on post lumbar disc surgery pain and prevention of severe pain-related complications and reduction of treatment costs and hospitalization period. Design of the study: a Randomized (with the Block of size 4), double blind, controlled, single-centered, phase 2 trial. Study population: Patients with lumbar disc disease. Inclusion criteria: Having discopathy without fusion. Exclusion criteria: Unwillingness to attend the study. Sample size: 70. Intervention or interventions: After receiving an informed consent and filling a questionnaire, the pain (by VAS) and vital signs will be measured one hour before the first dose of pain killer. Then, Tarooneh will be delivered to the patients in intervention group, 5 cc, 6, 12 and 24 hours after surgery (3 times) in addition to the usual treatments. The control group will receive the placebo instead of Tarooneh. One hour after receiving each dose, the pain status using Visual Analog Scale (VAS) and vital signs will be evaluated. Main outcome variables: Primary outcome: Pain Secondary outcomes: Blood pressure, Pulse rate, Breathing rate, temperature.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017063034815N1**
Registration date: **2017-09-27, 1396/07/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-09-27, 1396/07/05

Registrant information

Name

Zahra Shahsavari

Name of organization / entity

Arak University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Arak University of Medical Sciences.

Expected recruitment start date

2017-07-06, 1396/04/15

Expected recruitment end date

2017-11-06, 1396/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Clinical Trial to Compare the Effects of Oral Tarooneh and Placebo on Patients' Pain after Lumbar surgery

Public title

The effect of Tarooneh on pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age range 30 to 50 years; Having discopathy without fusion; Not fasting; Does not have a disease that increases or decreases pain; Do not breast-feed or be pregnant;Non-addiction;Specific underlying disease, such as heart disease;Tarooneh insensitivity.

Exclusion criteria:Unwillingness to attend the study; Transfer to another department.

Age
From **30 years** old to **50 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Block randomization method with four blocks will be used for randomization.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Student Ethics Committee, Arak University of Medical Sciences, Arak, Iran

Street address
Arak University of Medical Sciences, Alamoll Huda Street, Rah Ahan Street,

City
Arak

Postal code
3848176941

Approval date
2017-05-22, 1396/03/01

Ethics committee reference number
IR.ARAKMU.REC.1396.41

Health conditions studied

1

Description of health condition studied
lumbar pain

ICD-10 code
M54.5

ICD-10 code description
Low back pain

Primary outcomes

1

Description
pain

Timepoint
One hour before the intervention and 7,13 and 25 hours after the intervention

Method of measurement
Visual Analog Scale(vas)

Secondary outcomes

1

Description
Blood pressure

Timepoint
One hour before the intervention and 7,13 and 25 hours after the intervention.

Method of measurement
Sphygmomanometer.

2

Description
Temperature

Timepoint
One hour before the intervention and 7,13 and 25 hours after the intervention

Method of measurement
Centimeter using a thermometer

3

Description
heart beat

Timepoint
One hour before the intervention and 7,13 and 25 hours after the intervention

Method of measurement
pulse/min using a Puls Oximeter

4

Description
Breathing

Timepoint
One hour before the intervention and 7,13 and 25 hours after the intervention

Method of measurement
respiratory rate/ min by viewing

Intervention groups

1

Description
Intervention group: Tarooneh, 5 mg, orally, 3 times a day at 6, 12 and 24 hours after surgery.

Category

Placebo

2

Description
Control group: Distilled water, 5 mg, orally, 3 times a day at 6, 12 and 24 hours after surgery.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital
Full name of responsible person
Zahra SHahsavari
Street address
Valiasr Hospital, Vali Asr Square, Arak, Iran
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mojtaba Bagheri
Street address
Arak University of Medical Sciences, Sardasht, Arak, Markazi, Iran
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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
Arak 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
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Zahra SHahsavari
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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