

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

Iran (Islamic Republic of)

Phone

+98 86 3417 3502

Email address

z.shahsavari@arakmu.ac.ir

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

Arak

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

City

Arak

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

Arak University of Medical Sciences

Full name of responsible person

Zahra SHahsavari

Position

Student/MSc

Other areas of specialty/work

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www.arakmu.ac.ir; z.shahsavari@arakmu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Ahmad Reza Abedi

Position

Phd of nursing

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

Student/Masters

Other areas of specialty/work

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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