

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

The effect of preoperative Pentoxifylline administration on postoperative pain inpatients undergoing Laminectomy

Protocol summary

Study aim

Efficacy of Pentoxifylline in pain assessment after Laminectomy surgery

Design

The clinical trial with the control group, with parallel, double-blind, randomized, phase-referred groups, on 72 patients. www.randomization.com site is used for randomization.

Settings and conduct

In 1401, 72 patients will be included in the study in Shah Vali hospita haspital, the study will be double-blind, and the Pain Assessor and patient will be unaware of the grouping of patients. To blind the patients, placebo and for blinding the evaluator, the group encoding will be used in the form of a and b. One hour before surgery, one hour and 24 hours after surgery, pain levels will be evaluated in both groups using VAS. The reported pain is compared between the two groups and then compared.

Participants/Inclusion and exclusion criteria

Entry requirements: Patients who are candidates for Laminectomy surgery and are over 15 years old
Non-entry requirements: Patients with alcohol or substance abuse, patients who smoked, pregnant mothers, those with liver disease, diabetes, immunodeficiency (the use of immunosuppressive drugs or chemotherapy), AIDS, acute bowel disease, cancer, Children under the age of 15 and people older than 75 who are getting information from them are difficult.

Intervention groups

Intervention group "": In this group, one capsule of pentoxylline supplied by Farabi Pharmaceutical Company is given to the patient one hour before laminectomy.
"Control Group": In this group, one hour before laminectomy, a 400 mg capsule of pentoxylline whose contents are emptied and filled with starch is given to the patient.

Main outcome variables

The rate of pain based on the VAS

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220526054991N1**

Registration date: **2022-06-13, 1401/03/23**

Registration timing: **prospective**

Last update: **2022-06-13, 1401/03/23**

Update count: **0**

Registration date

2022-06-13, 1401/03/23

Registrant information

Name

Hamid Hobobati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

hh1358@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2022-09-06, 1401/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of preoperative Pentoxifylline administration on postoperative pain inpatients undergoing Laminectomy

Public title
The effect of Pentoxifylline in the treatment of pain in patients undergoing Laminectomy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients who are candidates for Laminectomy surgery and are over 15 years old.
Exclusion criteria:
Smoker Patients who have alcohol or substance abuse liver disease, diabetes, immunodeficiency (use of immunosuppressive drugs or chemotherapy), AIDS, acute bowel disease, cancer, and dialysis patients. Pregnant Children under the age of 15 and people older than 75 who are getting information from them is hard.

Age
From **15 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were randomly assigned to two groups by simple randomization method they are divided. How to select people and place them in dual groups It will be random, so after confirming the necessary conditions for the direction of Entering the study selected patients consecutively, the first patient in The first group will put the second patient in the second group. And so on. Again, the groups will take each patient to the limit. The number of samples in the intervention and control groups is equal.

Blinding (investigator's opinion)
Double blinded

Blinding description
Drugs studied by a neurosurger who does not have participated in the scheme , is prepared and in closed envelopes with the patient's code written on it Envelopes are preserved in the neurosurgical ward one day before surgery ; Day of surgery;The day after surgery by neurosurgeve that type of medication and The group where the patient is located does not know it opens. Nurses Patients and pain assessors are also unaware of the type of drug and the patient group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University_ Yazd Branch

Street address

Islamic Azad University, Alam Square,Shohadaye Gomnam Blvd

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Province

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Postal code

8915813135

Approval date

2022-02-21, 1400/12/02

Ethics committee reference number

IR.IAU.YAZD.REC.1400.062

Health conditions studied

1

Description of health condition studied

pain after Laminectomy

ICD-10 code

G89.1

ICD-10 code description

Acute pain, not elsewhere classified

Primary outcomes

1

Description

Severity of back pain

Timepoint

One hour before surgery, one hour after surgery and 24 hours after surgery

Method of measurement

Measurement of back pain based on Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: In this group, 36 eligible patients who are scheduled to undergo laminectomy and have been randomly assigned to this

group, one capsule of 400 mg pentoxylline product of Farabi Pharmaceutical Company will be given to the patient orally one hour before surgery, the number of tablets will be taken only once. And the possible complications will be monitored by attending the patient's bedside.

Category

Treatment - Drugs

2**Description**

Control group: In this group, 36 eligible patients who are scheduled to undergo laminectomy and have been randomly assigned to this group will be given a 400 mg pentoxylline capsule of Farabi Company whose contents are empty and filled with starch, one hour before surgery will be given to the patient orally, the capsule will be prepared from Farabi Pharmaceutical Company. The number of times you take the pill will only be once. And the possible complications will be monitored by attending the patient's bedside.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shah Vali Hospital

Full name of responsible person

Hamid Hobobati

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

Islamic Azad University

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**

Islamic Azad University

Full name of responsible person

Hamid Hobobati

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Hamid Hobobati

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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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

Demographic data and results of the research

When the data will become available and for how long

After the final report (2023)

To whom data/document is available

It will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Observing the author's right

From where data/document is obtainable

Call the inserted email and number.

What processes are involved for a request to access data/document

After submitting the request and reviewing it in the shortest possible time, they will be answered (one week)

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Hanieh Alsadat Fatemifar

Position

Intern

Latest degree

A Level or less

Other areas of specialty/work

Neurosurgery

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