

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effect of minocycline on postoperative pain after lumbar discectomy

Protocol summary

Study aim

Effect of minocycline on postoperative pain after lumbar discectomy

Design

Two arm parallel group randomized trial with blinded postoperative care and outcome assessment; with parallel groups and 40 patients in intervention group and 40 patients in control group.

Settings and conduct

In two different surgical centers of Imam Reza hospital and Tabriz shohada hospital, blindness was performed only on patients using placebo, and staff and surgeons, mediators and analyzers, etc. will be unaware of the two main arms of the study. Intervention was minocyclin tablet and placebo.

Participants/Inclusion and exclusion criteria

Criteria for entering the study: Age over 18 and under 70 years, Weight between 60 and 80 kilograms, Adaptation of symptoms and clinical signs with MRI findings. Exit criteria: History of previous lumbar surgery, Breastfeeding and pregnancy, Decisions to increase the scope of the surgery field, Alcoholism or drug abuse.

Intervention groups

The intervention group will receive the main drug and the placebo control group. The dosage will be 4 doses. A tablet will be given one day before the surgery, one tablet before surgery and one tablet after surgery procedure, and one tablet one day after the procedure. The minosylcine drug will be taken in the form of a 50-mg tablet of the Hexal company.

Main outcome variables

Lumbar pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120527009878N2**
Registration date: **2018-08-18, 1397/05/27**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-18, 1397/05/27**

Update count: **0**

Registration date

2018-08-18, 1397/05/27

Registrant information

Name

Firooz Salehpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 0830

Email address

salehpourf@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2019-03-11, 1397/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of minocycline on postoperative pain after lumbar discectomy

Public title

Evaluation the effect of minocycline in reducing postoperative pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 70 years Weight between 60 and 80 kilograms Conformity of clinical signs and symptoms with MRI findings Signed informed consent

Exclusion criteria:

Previous lumbar surgery History of alcohol or drug addiction Morphine complications during examination Pregnancy Breast feeding Decisions to increase the extent of surgery Use of analgesics over the last 24 hours Full improvement of neuropathic pain after surgery The presence of aphasia and visual impairment or illiteracy that prevents communication with the patient. Lumbar canal stenosis, Listeriosis, Infection, Spinal cord or bone tumors

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Selecting groups is completely random and will be done after matching. Randomization of patients will be done by file number using www.random.org site. On this site, the Gaussian randomization method was used with normal distribution.

Blinding (investigator's opinion)

Double blinded

Blinding description

The main intervention medication and placebo are both ordered by the HEXAL Company and will be completely alike.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tabriz University of Medical Science

Street address

Tabriz University of Medical Science , Gholghasht street , Azadi street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Approval date

2018-08-06, 1397/05/15

Ethics committee reference number

IR.TBZMED.REC.1397.386

Health conditions studied**1****Description of health condition studied**

Lumbar disc discectomy

ICD-10 code

M51.9

ICD-10 code description

Intervertebral disc disorder, unspecified

Primary outcomes**1****Description**

Lumbar pain after surgery

Timepoint

After surgery in recovery, one day after surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Minocycline tablet (50 mg) in 4 dose: one tablet one day before surgery, one tablet before surgery procedure, one tablet after surgery procedure, one tablet one day after surgery.

Category

Treatment - Surgery

2**Description**

Control group: Placebo tablet, (50 mg) in 4 dose: one tablet one day before surgery, one tablet before surgery procedure, one tablet after surgery procedure, one tablet one day after surgery.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Neurosurgery Ward of Shohada hospital
Full name of responsible person
Sajjad Ghaemi
Street address
Gholshahr Ave, Shahgoli Blvd
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East Azarbaijan
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Email
shohadahospital@tbzmed.ac.ir
Web page address
<https://shohadahosp.tbzmed.ac.ir/>

2

Recruitment center

Name of recruitment center
Neurosurgery Ward of Emem Reza hospital
Full name of responsible person
Mir Sajjad Ghaemi
Street address
Daneshghah Ave, Pishghadam Blvd
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<https://imamreza.tbzmed.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Shimya
Street address
Vice Chancellor for Research , Faculty of Medicine ,
Gholghasht Street, Azadi Street, Tabriz

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Fax

+98 41 3337 6923

Email

info@medfac.tbzmed.ac.ir

Web page address

<https://medfac.tbzmed.ac.ir/>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Firoz Salehpoor

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

Street address

Neurosurgery ward, Emam Reza Hospital, Gholghasht Street, Azadi Street, Tabriz

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Firoz Salehpoor

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Web page address

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

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

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 encoded and unidentified data can be provided to other researchers.

When the data will become available and for how long

After the paper is published, the project is accessible.

To whom data/document is available

Individuals with organizational characteristics of the Academic Research Center

Under which criteria data/document could be used

Data can only be used for statistical analysis purposes with new studies

From where data/document is obtainable

To receive the data, you can refer to the responsible respondent.

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

After coordination with the responsible person and approval of the research committee and the vice chancellor of the research center are available.

Comments

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Firoz Salehpoor

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

Street address

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