

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of pregabalin on the prevention of succinylcholine-induced fasciculation and myalgia

Protocol summary

Study aim

The purpose of this study will be to assess the effect of pregabalin on the prevention of succinylcholine induced fasciculation and myalgia

Design

Clinical trial with two arm parallel groups, randomised trial with double blinded assessment. Study phase will be 3-2.

Settings and conduct

In Urmia Imam Khomeini hospital operating room after induction of anesthesia the incidence of fasciculation will be evaluated and recorded. The incidence and severity of myalgia will be measured 6, 12, 18, and 24 hours after surgery.

Participants/Inclusion and exclusion criteria

inclusion criteria: aged 20 to 60 years old, by American Society of Anesthesiologists class I and II exclusion criteria: Patients with BMI above 25 kg/m², history of central nervous system disease, renal dysfunction, history of allergy to any of the drugs used during the study, history of peptic ulcer disease and antacid therapy, and patients who used analgesic drug within 24 hours before surgery, used any kind of sedative drug, patients with a history of taking antidepressants and calcium channel blockers, patients who had contraindication for succinylcholine, and patients whose laparoscopic cholecystectomy was replaced with open cholecystectomy

Intervention groups

In the intervention group, patients will be received pregabalin 300mg and in control group, patients will be received placebo oral, 30 minutes before the operation.

Main outcome variables

fasciculation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160430027677N11**

Registration date: **2019-01-22, 1397/11/02**

Registration timing: **retrospective**

Last update: **2019-01-22, 1397/11/02**

Update count: **0**

Registration date

2019-01-22, 1397/11/02

Registrant information

Name

Shahryar Sane

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 3223 4897

Email address

sane.sh@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-06-21, 1396/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of pregabalin on the prevention of succinylcholine-induced fasciculation and myalgia

Public title

Evaluation the effect of pregabalin on succinylcholine fasciculation and myalgia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

aged 20 to 60 years old American Society of Anesthesiologists class I and II

Exclusion criteria:

Patients with BMI above 25 kg/m² history of central nervous system disease renal dysfunction history of allergy to any of the drugs used during the study history of peptic ulcer disease and antacid therapy patients who used analgesic drug within 24 hours before surgery used any kind of sedative drug patients with a history of taking antidepressants and calcium channel blockers patients who had contraindication for succinylcholine patients whose laparoscopic cholecystectomy will be replaced with open cholecystectomy

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned into two groups of pregabalin 300 mg (group PG) and placebo (group P) using Random Allocation Software 2.0, and the target codes will be written and placed in sealed envelopes with sequential allocation using double-blind method.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drug will be administered by the nurse in the ward and at the time of admission, the anesthesiologist will be unaware of which patient will be assigned to which group. Drug containers will be identical and only the nurse will know about the contents of each of them, and finally, after collecting information from the anesthesia residents, the anesthesiologist will be informed of the group each patient will be assigned to.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

Emergent Street, Ershad Avenue

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2016-10-26, 1395/08/05

Ethics committee reference number

IR.UMSU.REC.1395.308

Health conditions studied

1

Description of health condition studied

fasciculation

ICD-10 code

R25.3

ICD-10 code description

Fasciculation

Primary outcomes

1

Description

fasciculation

Timepoint

Immediately after injection of succinylcholine

Method of measurement

visual analog scale

Secondary outcomes

1

Description

incidence of myalgia

Timepoint

6, 12, 18, and 24 hours after surgery

Method of measurement

visual analog scale

2

Description

severity of myalgia

Timepoint

6, 12, 18, and 24 hours after surgery

Method of measurement

visual analog scale

Intervention groups

1

Description

Intervention group: will be received Pregabalin 300 mg tablet oral placebo 30 minutes before surgery.

Category

Prevention

2

Description

Control group: will be received placebo 30 minutes before surgery.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Khomeini Hospital, operating room

Full name of responsible person

Shahryar Sane

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Ershad Avenue, Modarres Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Iraj Mohebbi

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research@umsu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Shahryar Sane

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

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

Oroumia University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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