Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 knew 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 commitee 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
Street address
Ershad Avenue, Modarres Avenue
City
Urmia
Province
West Azarbaijan
Postal code
5715781351
Phone
+98 44 3346 9931
Fax
+98 44 3346 8967
Email
emam-h-urm@umsu.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Iraj Mohebbi
Street address
Emergent Street, Ershad Avenue
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3223 4897
Fax
+98 44 3223 4897
Email
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
Street address
Emergrnt Street, Resalat Avenue
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3223 4897
Fax
+98 44 3346 8967
Email
sanesh@umsu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Shahryar Sane
Position
Associate professor

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Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3223 4897
Fax
+98 44 3346 8967
Email
sanesh@umsu.ac.ir

Person responsible for updating data

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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City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3223 4897
Fax
+98 44 3346 8967
Email
sanesh@umsu.ac.ir

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