Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Survey of the effect of gabapentin on post-operative pain of shoulder rotator cuff surgery

Protocol summary

Study aim
Survey of the effect of gabapentin on post-operative pain of shoulder rotator cuff surgery

Design
Double blinded randomized clinical trial

Settings and conduct
Intervention group: Patients in group G will receive 300 mg of gabapentin at 6 pm on the first day after surgery and 600 mg of gabapentin in divided doses at 6 am and 6 pm on the second and third days. Control group: Patients in group P will receive one placebo on the first day after surgery at 6 pm and on the second and third days after taking placebo in two divided doses at 6 am and 6 pm.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Patients undergoing shoulder rotator cuff surgery ,Age 30-65 years old, (ASA) I-II. Exclusion criteria:Sensitivity to gabapentin History of hypertension Heart disease Liver and kidney disease Acute or chronic pain associated with other areas of the body Any dependence on narcotics and psychotropic drugs Continuous use of tranquilizers for depression and anxiety disorders and seizure disorders.

Intervention groups
Intervention group: Patients in group G will receive 300 mg of gabapentin at 6 pm on the first day after surgery and 600 mg of gabapentin in divided doses at 6 am and 6 pm on the second and third days. Control group: Patients in group P will receive one placebo on the first day after surgery at 6 pm and on the second and third days after taking placebo in two divided doses at 6 am and 6 pm.

Main outcome variables
Pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100127003213N9**
Registration date: **2020-05-19, 1399/02/30**
Registration timing: **prospective**

Last update: **2020-05-19, 1399/02/30**
Update count: **0**

Registration date
2020-05-19, 1399/02/30

Registrant information

Name
Arash Farbood

Name of organization / entity
Shiraz University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 71 1233 7636

Email address
farboda@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-09, 1399/03/20

Expected recruitment end date
2020-08-10, 1399/05/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Survey of the effect of gabapentin on post-operative pain of shoulder rotator cuff surgery

Public title
Survey of the effect of gabapentin on post-operative pain of shoulder rotator cuff surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients undergoing shoulder rotator cuff surgery Age 30-65 years old (ASA) I-II
Exclusion criteria:
Sensitivity to gabapentin History of hypertension Heart disease Liver and kidney disease Acute or chronic pain associated with other areas of the body Any dependence on narcotics and psychotropic drugs Continuous use of tranquilizers for depression and anxiety disorders and seizure disorders
Age
From **30 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Balanced block randomization
Blinding (investigator's opinion)
Double blinded
Blinding description
The nurse prescribing the medication, the patient, and the data collector will be unaware of the patient's study group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Vice chancellor of research,7th floor of central building of Shiraz University of Medical Sciences, Zand street
City
Shiraz
Province
Fars
Postal code
7134844119
Approval date
2020-01-21, 1398/11/01
Ethics committee reference number
IR.SUMS.MED.REC.1398.572

Health conditions studied

1

Description of health condition studied
Shoulder rotator cuff surgery
ICD-10 code
M75.1
ICD-10 code description
Rotator cuff tear or rupture, not specified as traumatic

Primary outcomes

1

Description
Pain
Timepoint
The severity of pain is measured by Numeric Rating Scale , every 2 hours to 6 hours, and then every 6 hours to 24 hours.
Method of measurement
Numeric Rating Scale (NRS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in group G will receive 300 mg of gabapentin at 6 pm on the first day after surgery and 600 mg of gabapentin in divided doses at 6 am and 6 pm on the second and third days.
Category
Treatment - Drugs

2

Description
Control group: Patients in group P will receive one placebo on the first day after surgery at 6 pm and on the second and third days after taking placebo in two divided doses at 6 am and 6 pm.
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Chamran Hospital

Full name of responsible person
Samira Safari

Street address
Shahid Chamran Hospital, Chamran Boulevard

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Shiraz

Province
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1564471948

Phone
+98 71 3624 0101

Email
chamranhosp@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr Younes Ghasemi

Street address
Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand street

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7134844119

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sacrc@sums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Samira Safari

Position
Anesthesiology resident/physician

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

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Anesthesiology Department, Faghihi Hospital, Zand Street

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
Anesthesiologist/Pain Fellowship

Latest degree
Subspecialist

Other areas of specialty/work
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arashfarbood@yahoo.com

Person responsible for updating data

Contact

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Full name of responsible person
Arash Farbood
Position
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Latest degree
Subspecialist
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Its against our policy.
Study Protocol
No - There is not 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
No - There is not 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