

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jul 2026

### Effect Of Preemptive Gabapentin On Postoperative Pain Management After VATS Surgery

#### Protocol summary

##### Study aim

to evaluate the effect of gabapentin in reducing pain and reduce the use of opioids after VATS surgery

##### Design

One hundred patients candidate for VATS surgery at Masih Daneshvari Hospital will included. Patients will randomly divided into two groups of control and intervention. Group allocation was concealed by assigning a unique code to each participants. Simple randomization will be used.

##### Settings and conduct

Masih Daneshvari Hospital, Tehran, Iran Patients and health care providers are blinded.

##### Participants/Inclusion and exclusion criteria

inclusion criteria: between 18 and 65 years proper physical condition for VATS surgery exclusion criteria: gabapentin allergy, renal failure, hepatic failure, nervous and mental disorders, history of cardiovascular surgeries, pregnant and breastfeeding women

##### Intervention groups

Patients will randomly divided into two groups of 50 of control and intervention. One group receives two 300mg gabapentin capsules on the night before operation and two more an hour before surgery. The control group receives two placebo capsules on the night before operation and two more an hour before surgery.

##### Main outcome variables

Visual Analogue Scale

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160813029327N12**

Registration date: **2018-06-10, 1397/03/20**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-06-10, 1397/03/20**

Update count: **0**

##### Registration date

2018-06-10, 1397/03/20

##### Registrant information

###### Name

Ramin Abrishami

###### Name of organization / entity

Islamic Azad University, Pharamceutical sciences branch

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2264 1889

###### Email address

r\_abrishami@iaups.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Researcher

##### Expected recruitment start date

2017-11-01, 1396/08/10

##### Expected recruitment end date

2018-08-01, 1397/05/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect Of Preemptive Gabapentin On Postoperative Pain Management After VATS Surgery

##### Public title

Effect Of Preemptive Gabapentin On Postoperative Pain Management After VATS Surgery

##### Purpose

Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
between 18 and 65 years proper physical condition for VATS surgery

**Exclusion criteria:**  
gabapentin allergy renal failure hepatic failure nervous and mental disorders history of cardiovascular surgeries pregnant and breastfeeding women

**Age**  
From **18 years** old to **65 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**  
Target sample size: **100**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Simple randomization

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
In this study patients and health care providers will be blind

**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 of Pharmaceutical Sciences

**Street address**  
#99, Yakhchal Ave, Shariati st, tehran ,Iran

**City**  
Tehran

**Province**  
Tehran

**Postal code**  
1941933111

**Approval date**  
2017-05-08, 1396/02/18

**Ethics committee reference number**  
IR.IAU.PS.REC.1396.73

## Health conditions studied

### 1

#### Description of health condition studied

Respiratory disease

#### ICD-10 code

J40-J47,J0

#### ICD-10 code description

Chronic lower respiratory diseases,Diseases of the respiratory system,Other diseases of upper respiratory tract,Other diseases of pleura

## Primary outcomes

### 1

#### Description

Pain assessment

#### Timepoint

each 30 minutes and then 2, 4, 6, 10 and 24 hours after operation

#### Method of measurement

VAS technique

### 2

#### Description

opioid rate of consumption

#### Timepoint

up to 24 hours after operation

#### Method of measurement

Based on nursing chart

### 3

#### Description

ketorolac rate of consumption

#### Timepoint

up to 24 hours after operation

#### Method of measurement

Based on nursing chart

### 4

#### Description

first analgesic need time

#### Timepoint

first analgesic need time after surgery

#### Method of measurement

Based on nursing chart

## Secondary outcomes

### 1

#### Description

adverse reactions

#### Timepoint

up to 24 hours after operation

#### Method of measurement

questionnaire

## Intervention groups

### 1

#### Description

interventional group receives two 300mg gabapentin capsules on the night before operation and two more an hour before surgery.

#### Category

Prevention

### 2

#### Description

The control group receives two placebo capsules on the night before operation and two more an hour before surgery.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Masih Daneshvari Hospital

##### Full name of responsible person

Behrooz Farzanegan

##### Street address

Daarabad ,Niavaran , Tehran

##### City

tehran

##### Province

Tehran

##### Postal code

1956944413

##### Phone

+98 21 2712 3000

##### Email

farzaneganbehrooz@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Farshad Hashemian

##### Street address

Yakhchal St, IAUPS

##### City

Tehran

##### Province

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##### Postal code

1941933111

##### Phone

+98 21 2263 3986

##### Email

fhashemian@yahoo.com

#### 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

Masih Daneshvari Hospital

##### Full name of responsible person

Behrooz Farzanegan

##### Position

Assistant professor,Anesthesiologist,Fellowship of Critical Care Medicine

##### Latest degree

Specialist

##### Other areas of specialty/work

Anesthesiology

##### Street address

Daarabad ,Niavaran , Tehran

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##### Province

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##### Fax

##### Email

farzaneganbehrooz@gmail.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Ramin Abrishami

##### Position

PhD,Assistant professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Clinical Pharmacy  
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r\_abrishami@iaups.ac.ir  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Media Shamsaddini  
**Position**  
student  
**Latest degree**  
A Level or less  
**Other areas of specialty/work**  
Medical Pharmacy  
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media.1372@gmail.com  
**Web page address**

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

### Clinical Study Report

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

### Analytic Code

Not applicable

### Data Dictionary

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

### Title and more details about the data/document

Patients' demographic data, Visual Analogue Scale, Opioid consumption

### When the data will become available and for how long

After publication of paper, for one year

### To whom data/document is available

To academic persons

### Under which criteria data/document could be used

User should cite the primary document

### From where data/document is obtainable

Via email to corresponding author

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

Sending email to corresponding author

### Comments