

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### The effect single dose of pregabalin on post tracheal intubation sore throat after general anesthesia

#### Protocol summary

2015-06-22, 1394/04/01

#### Summary

our aim in this study is the evaluating the effect of pregabalin on post tracheal intubation sore throat after general surgery.this is a double blind and randomized clinical trial.in this study sixty patients candidate for urologic and general surgery will be included in the study after qualifying the inclusion and exclusion criteria and obtaining the informed consent.Inclusion criteria:all 20-60 years patient candidate for urologic and general surgery.Exclusion criteria:1-NSAIDs intake in two week before surgery 2-history of sore throat and upper respiratory tract infection3-difficult intubation4-long surgery time more than 3 hours5-drug allergy6-addiction7-psychotic patient8-defective positionpatients will be divided to two group of thirty(A,B).A group patients will recieve a lyrica tab 300 mg and B group patients will recieve placebo one hour before intubation. patients will be extubated at the end of surgery.sore throat severity will be measured with VAS at 2,6,24 hour after consiousness by a person who was unaware about grouping.data will be analyzed by descriptive statistic test,mean difference test for indeppendent group, frequent measurment RMA test,chi-square test with spss 15 statistic soft ware.  $p < 0.05$  will be significantly.data normality will be evaluated by Q-Q wave and colmogrov-smirnov test.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015031416956N4**

Registration date: **2015-06-22, 1394/04/01**

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

Last update:

Update count: **0**

##### Registration date

#### Registrant information

##### Name

Hassan Mohammadipour Anvari

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3334 7054

##### Email address

dr.anvari22@yahoo.com

#### Recruitment status

##### Recruitment complete

#### Funding source

Tabriz university of Medical Sciences

#### Expected recruitment start date

2015-04-04, 1394/01/15

#### Expected recruitment end date

2015-07-06, 1394/04/15

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect single dose of pregabalin on post tracheal intubation sore throat after general anesthesia

#### Public title

The effect single dose of pregabalin on post tracheal intubation sore throat after general anesthesia

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

Inclusion criteria:all 20-60 years patient candidate for urologic and general surgery.Exclusion criteria:1-NSAIDs

intake in two week before surgery 2-history of sore throat and upper respiratory tract infection3-difficult intubation4-long surgery time more than 3 hours5-drug allergy6-addiction7-psychotic patient8-defective position

#### Age

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

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **60**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tabriz University of Medical Sciences

##### Street address

Tabriz, Azadi street,Golgash street

##### City

tabriz

##### Postal code

#### Approval date

2015-02-15, 1393/11/26

#### Ethics committee reference number

92/3-4/10

## Health conditions studied

### 1

#### Description of health condition studied

post tracheal intubation sore throat after general anesthesia

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

sore throat

#### Timepoint

recovery,2,6 and 24 hours after

#### Method of measurement

VAS

## Secondary outcomes

### 1

#### Description

vertigo

#### Timepoint

daily

#### Method of measurement

graded questionnaire

### 2

#### Description

visual disorder

#### Timepoint

daily

#### Method of measurement

graded questionnaire

### 3

#### Description

oedema

#### Timepoint

daily

#### Method of measurement

graded questionnaire

## Intervention groups

### 1

#### Description

intervention group will receive A pregabalin (Lyrica) tab 300 mg with 50 ml water one hour before anesthesia.

#### Category

Treatment - Drugs

### 2

#### Description

control group will receive placebo with 50 ml water

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Reza Hospital

**Full name of responsible person**  
Dr.Hasan Mohammadi pour Anvari  
**Street address**  
**City**  
tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Vice Chancellor for research of Tabriz Faculty of Medical Sciences  
**Full name of responsible person**  
Dr. Hasan Soleimanpour  
**Street address**  
Tabriz University of Medical Sciences, Medical Faculty,Vice Chancellor for research  
**City**  
Tabriz

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Vice Chancellor for research of Tabriz Faculty of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

*empty*

#### Domestic or foreign origin

*empty*

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences  
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Afsaneh Khobeideh  
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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

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## Sharing plan

#### Deidentified Individual Participant Data Set (IPD)

*empty*

#### Study Protocol

*empty*

#### Statistical Analysis Plan

*empty*

#### Informed Consent Form

*empty*

#### Clinical Study Report

*empty*

#### Analytic Code

*empty*

#### Data Dictionary

*empty*