

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The preemptive effect of a single dose of Pregabalin (Lyrica 300) for post operative pain control after Mandibular fracture surgery

Protocol summary

Summary

Adjuvant drugs such as Gabapentin can reduce postoperative pain killer opioids dose. The aim of this study was to evaluate Pregabalin effect on post operative pain in mandibular fractures operations. In a double -blind clinical trial in 60 patients during 2012-2013 years with mandibular fracture operation were divided randomly into two groups of 30 after obtaining the informed consent about Lyrica. Inclusion criteria were age between 20-60 years, candidate for Mandibular fracture operation and exclusion criteria were drug addiction, history of pain killer drugs, drug sensitivity and patient's lack of consent. One hour before anesthesia, Lyrica 300mg capsule was given with 50 ml water to the patients at the beginning in group A. In the operating room premedication were given with Fentanyl and Midazolam. Induction was performed with Propofol then Cis-atracurium were given and intubated. Anesthesia was continued with Total Intravenous Anesthesia method by Propofol and Remifentanyl. Group B did not received capsule and had same method of anesthesia.. Reverse patients were extubated and sent to the recovery after surgery. Pain scoring by ruler (Visual Analogue Scale) , level of analgesics consumption (Morphine or Pethidine) based on mg (VAS) over 3 were registered to 24 hours at times 0, 2, 6, 12 and 24 after consciousness. The findings were analyzed and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202281772N10**

Registration date: **2013-09-12, 1392/06/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-09-12, 1392/06/21

Registrant information

Name

Dawood Aghamohammadi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1381 8940

Email address

aghamohammadid@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Science - Research team of anesthesiology

Expected recruitment start date

2012-07-22, 1391/05/01

Expected recruitment end date

2013-07-23, 1392/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The preemptive effect of a single dose of Pregabalin (Lyrica 300) for post operative pain control after Mandibular fracture surgery

Public title

The preemptive effect of a single dose of Pregabalin (Lyrica 300) for post operative pain control after Mandibular surgery

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion criteria: were age between 20-60 years;
candidate for Mandibular fracture operation
exclusion criteria: were drug addiction; history of pain killer drugs;
drug sensitivity and patient's lack of consent.

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
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Vice chancellor for research

Street address
Faculty of medicine, Vice chancellor for research,
Daneshghah street

City
Tabriz

Postal code

Approval date
2012-07-22, 1391/05/01

Ethics committee reference number
5/4/9277

Health conditions studied

1

Description of health condition studied
Fracture of mandible

ICD-10 code
S02.6

ICD-10 code description
Fracture of mandible

Primary outcomes

1

Description
pain

Timepoint
2, 6, 12, 24 o'clock postoperative

Method of measurement
visual analogue scale

Secondary outcomes

1

Description
Analgesic drugs

Timepoint
2, 6, 12, 24 o'clock postoperative

Method of measurement
Milligram/ Dose

Intervention groups

1

Description
Using Lyrica 300mg capsule One hour before anesthesia,
in the intervention group

Category
Treatment - Drugs

2

Description
Without taking Lyrica 300mg capsule One hour before
anesthesia, in the control group

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza teaching Hospital

Full name of responsible person
Dawood aghamohammadi

Street address

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Science - Research team
of anesthesiology

Full name of responsible person

Mahain Seidhejazie

Street address

Third floor, Research team of anesthesiology, Faculty of Medicine, Daneshghah Street

City

Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz University of Medical Science - Research team of anesthesiology

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**

Anesthesiology Dept

Full name of responsible person

Dawood Aghamohammadi

Position

Associated Professor

Other areas of specialty/work**Street address**

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Anesthesiology Dept

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Full name of responsible person

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Web page address**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