

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Preoperative single dose of oral Amantadine for acute and chronic post operative pain control in Mandibular fracture

Protocol summary

Summary

Background and Objectives: Post- Traumatic pain after maxillofacial fracture is one of the several factors that led to numerous complication and increases in morbidity. Pre-emptive analgesia can help in controlling the pain via different mechanisms. This study intends to determine if this method could reduce post operative pain and complications as well as the amount of post operative analgesics requirements. Design: Sixty patients With mandibular fracture who are candidate for open reduction with intra oral approach , will be recruited. Main inclusion criteria are patients under going open reduction with intra oral approach for mandibular fracture and main exclusion criteria are History of addiction , Seizure and psychopathic conditions. After providing written consent form, they will be randomly divided into the two groups: study group will undergo pre-emptive analgesia (Amantadine capsule 100 mg), while the control group will receive placebo. At the end of the study two groups will be compared in terms of pain and analgesic consumption at various times after operation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201406201772N13**
Registration date: **2014-06-27, 1393/04/06**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-06-27, 1393/04/06

Registrant information

Name

Dawood Aghamohammadi

Name of organization / entity

Tabriz University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research / Tabriz Medical University

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2015-03-18, 1393/12/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Preoperative single dose of oral Amantadine for acute and chronic post operative pain control in Mandibular fracture

Public title

post operative pain control

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion: age from 20 to 60 people who are going to have open reduction for mandibular fracture Exclusion criteria : Addiction, Seizure, psychopathic conditions and refuse to participate.

Age

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

Gender

Both

Phase

3

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 science , reseach ethical committee

Street address

Daneshghah street/ Tabriz university of medical science/Fuculty of Dentistry/ ethical committee

City

Tabriz

Postal code**Approval date**

2010-08-20, 1389/05/29

Ethics committee reference number

934

Health conditions studied**1****Description of health condition studied**

post operative pain control

ICD-10 code

Y46.7

ICD-10 code description

Antiparkinsonism drugs

Primary outcomes**1****Description**

Pain

Timepoint

0, 2, 4, 6, 12 and 24 hours after operation

Method of measurement

Visual Analogue Scale

Secondary outcomes**1****Description**

Opioid consumption

Timepoint

0, 2, 4, 6, 12 and 24 hours after operation

Method of measurement

Total Dose

Intervention groups**1****Description**

Control group: instead of Amantadine capsule, recived placebo before the operation

Category

Treatment - Drugs

2**Description**

Intervention group received Amantadine capsule 100 mg, 1-2 hours before surgery

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Reza Hospital/Tabriz

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/ Vice chancellor of reseach

Full name of responsible person

Dawood Aghamohammadi

Street address

Daneshghah street/ Tabriz university of medical science/ Faculty of medicin

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/ Vice chancellor of reseach
Proportion provided by this source
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

2

Sponsor
Name of organization / entity
Tabriz university of medical science/ Vice chancellor of reseach
Full name of responsible person
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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 science/fuculty of medicin/ Anesthesiology Dept
Full name of responsible person
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Position
associated Professor
Other areas of specialty/work

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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