Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Iran (Islamic Republic of)

Phone

+98 41 1381 8940

Email address

aghamohammadid@tbzmed.ac.ir

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 cosumption
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/ Fuculty 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
Dawood Aghamohammadi
Street address
Daneshghah street/ Tabriz university of medical science/ Fuculty 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

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
Dawood Aghamohammadi
Position
associated Professor
Other areas of specialty/work
Street address
Daneshghah street/ Tabriz university of medical science//fuculty of medicin/ Anesthesiology Dept
City
Tabriz
Postal code
Phone
+98 41 1381 8940
Fax
Email
aghamohammadid@tbzmed.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz university of medical science/fuculty of medicin/ Anesthesiology Dept
Full name of responsible person
Dawood Aghamohammadi
Position
Associated Professor
Other areas of specialty/work
Street address
Daneshghah street/ Tabriz university of medical science/ Fuculty of medicin Tabriz
City
Tabriz
Postal code
Phone
+98 41 1381 8940
Fax
Email
aghamohammadid@tbzmed.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tabriz university of medical science/fuculty of medicin/ Anesthesiology Dept
Full name of responsible person
Dawood Aghamohammadi
Position
Associated Professor
Other areas of specialty/work
Street address
Daneshghah street/ Tabriz university of medical science//fuculty of medicin/ Anesthesiology Dept
City
Tabriz
Postal code
Phone
+98 41 1381 8940
Fax
Email
aghamohammadid@tbzmed.ac.ir
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