Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Pain releif effect of intravenous acetaminophen and pethidine in maxillofacial surgery

Protocol summary

Summary

In a double-blind randomized-controlled trial we wanted to assess the efficacy of intravenous acetaminophen in controlling early postoperative pain in maxillofacial inpatient operations compared to routinely administered opioids. We studied 50 consecutive patients. All patients had an operation on their mandible. The patients were randomly divided into two groups by simple randomization. Postoperative pain was measured by visual analogue score (VAS) 1, 2, 4, 8, 12 and 24 hours after the operation. The first group (25 patients) received postoperative pethidine 1 mg per kg every 4 hours while the second group (25 patients) received postoperative acetaminophen 15 mg per kg every 6 hours.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307104731N12**
Registration date: **2013-07-18, 1392/04/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-07-18, 1392/04/27

Registrant information

Name

Hamze Hosseinzade

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1334 7055

Email address

hosseinz@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Dental and Periodontal Research Center-Tabriz University of Medical Sciences,Tabriz,Iran

Expected recruitment start date

2013-06-22, 1392/04/01

Expected recruitment end date

2013-08-23, 1392/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Pain releif effect of intravenous acetaminophen and pethidine in maxillofacial surgery

Public title

Pain releif effect of intravenous acetaminophen and pethidine in maxillofacial surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: patients that need mandibular surgery; having 18-50 years old; without systemic disease; without other organs injury. exclusion criteria: history of allergy to pethrdine and acetaminophen; alcohol consumers; drug abusers; psycologic disease; Monoaminoaxidase (MAO)inhibitors consumers; history of chronic pain; surgery time over 2 hours.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

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

Tabriz University of Medical Sciences Ethics Committee

Street address

Tabriz University of Medical Sciences

City

Tabriz

Postal code

Approval date

2013-04-20, 1392/01/31

Ethics committee reference number

928

Health conditions studied

1

Description of health condition studied

Oral and maxillofacial surgery

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Maxillofacial surgeries

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain severity

Timepoint

Before and 24 hours after intervention

Method of measurement

Visual Analogue Scale(VAS)

Secondary outcomes

empty

Intervention groups

1

Description

intrvention: use of intravenous acetaminophen intervention group: using intravenous acetaminophen in contrast routine pethedine in interventin group we change postoperative analgesic drug to intravenous acetaminophen

Category

Treatment - Drugs

2

Description

Control group: using routine pethedine in cotrol group we use routine opiod analgesic drug (pethedine) without change in dose or administration route.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital- Tabriz

Full name of responsible person

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research center of Dental Faculty- Dental and Periodontal Research Center

Full name of responsible person

Kheyraddin Pourabbas

Street address

3rd floor, Dental Faculty of Tabriz, Golgasht st.

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research center of Dental Faculty- Dental and Periodontal Research Center

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

Department of Maxillofacial Surgery, Faculty of Dentistry , Tabriz University of Medical Sciences

Full name of responsible person

Javad Yazdani

Position

Associate professor

Other areas of specialty/work

Street address

Department of Maxillofacial Surgery, Faculty of Dentistry , Tabriz University of Medical Sciences

City

Tabriz

Postal code

Phone

+98 41 1335 5968

Fax

Email

m_ghavimi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Maxillofacial Surgery, Faculty of Dentistry , Tabriz University of Medical Sciences

Full name of responsible person

Javad Yazdani

Position

Associate professor

Other areas of specialty/work

Street address

Department of Maxillofacial Surgery, Faculty of Dentistry , Tabriz University of Medical Sciences

City

Tabriz

Postal code

Phone

+98 41 1335 5968

Fax

Email

Ja-yazdani@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Javad Yazdani

Position

Associated Professor of OMFS

Other areas of specialty/work

Street address

Dental faculty of Tabriz

City

Tabriz

Postal code

00984113355967

Phone

+98 41 1335 5967

Fax

Email

m_ghavimi@yahoo.com

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