

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

A Clinical trial of paracetamol administration after maxillofacial surgery in Post-operative opioid requirements.

Protocol summary

Summary

Objectives: Paracetamol is one of the cyclooxygenase inhibitors which is used for pain relief after surgery. Controlling postoperative pain after surgery is one of the complex challenges of the health system and may be a conflict between doctors and patients. Therefore, using low-risk and non-opioid drugs with fewer complications will enhance users' satisfaction and safety. **Design:** By a questionnaire, personal information, history of smoking, consumption of the NSAIDs, history of allergy to drugs, type of medication or surgery and duration of general anesthesia were reported. Severity of pain was evaluated by visual analogue scale (VAS) (100-mm) and the amount of using opioid which was used after surgery, was recorded in ward. **Methods:** The patients were allocated to odd and even groups and they gave their informed consent for the injection of IV paracetamol. The patients were explained about the type of drug and its possible complications and how their postoperative pain was measured. Inclusion criteria were 1) 15 to 45-year-old patients, and 2) class I patients (ASA) and the exclusion criteria were 1) the patients out of age range of 15 to 45 years, 2) patients other than class I. The same premedication, anesthesia induction and the maintenance of the anesthesia was used for both groups. After preparation for induction of anesthesia and infusion of muscle relaxant, the patient was intubated by a fiberoptic device. After surgery and transferring patient to recovery room and regaining the patient full consciousness, pain was measured. **Interventions:** Immediately after surgery, IV-paracetamol was infused (15 mg/Kg in 100cc of normal saline during 10 minutes as single dose) in recovery room. Blood pressure, heart rate and O₂ Saturation were also recorded. **Main outcome measures:** Hemodynamic information of the patient in recovery room and pain, that was measured by visual analogue scale 100-mm, were evaluated. Pain was measured 12 hours after injection of paracetamol and using opioids was also evaluated after 24 hours by VAS

100-mm. Patient's level of satisfaction was evaluated as poor (0), moderate (1), good (2), and excellent (3). Finally, the medication side effects such as nausea, vomiting, gastrointestinal upset, allergic reactions, urinary retention, diarrhea, and constipation were evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138711221674N1**

Registration date: **2012-01-28, 1390/11/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-01-28, 1390/11/08

Registrant information

Name

Hamid Reza Eftekharian

Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellery of Research and Technology, Shiraz University Of Medical Sciences

Expected recruitment start date

2011-12-22, 1390/10/01

Expected recruitment end date

2012-12-21, 1391/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Clinical trial of paracetamol administration after maxillofacial surgery in Post-operative opioid requirements.

Public title

The effect of intravenous acetaminophen in reducing Post-operative opioid requirements after maxillofacial surgery.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 15 to 45-year-old patients; and class I patients (ASA) Exclusion criteria: The patients out of age range of 15 to 45 years; patients other than class I (ASA)

Age

From **15 years** old to **45 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

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**

Ethics committee Of Shiraz University Of Medical Sciences

Street address

Vice-Chancellery of Research and Technology, Shiraz University of Medical Sciences, Zand Avenue.

City

Shiraz

Postal code

71345-1978

Approval date

2011-09-23, 1390/07/01

Ethics committee reference number

CT-90-5792

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

Maxillofacial Surgery(correction after injury)

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Patient's hemodynamic data are evaluated in recovery room.

Timepoint

12 hours after injection of paracetamol

Method of measurement

Blood pressure and heart rate were evaluated by digital monitoring devices.

2**Description**

pain of patients were measured.

Timepoint

first , second, fourth, sixth, eighth, tenth, twelfth hour

Method of measurement

visual analog scale (100-mm)

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

Patient's satisfaction

Timepoint

12 hrs. and 24 hrs. after injection

Method of measurement

questionnaire which evaluated as poor(0), moderate(1), good(2), excellent(3).

2**Description**

medication's side effects such as nausea, vomiting, gastrointestinal upset, allergic reactions, urinary retention, diarrhea, constipation was noted.

Timepoint

12 hrs. and 24 hrs. after injection

Method of measurement

Through a questionnaire that contains information about the drug side effects

Intervention groups

1

Description

Equal to 50 divided randomly into two groups, so that odd numbers - received paracetamol (Group A) and even numbers - receiving placebo (group II) are divided. Complete questionnaires in the surgery's not the type of drug (double blind). After transfer the patient to the recovery room and extubation of trachea, and eventually the patient returned to full consciousness, with relation to the patient's pain is measured and recorded. An intravenous infusion of the paracetamol up to one gram in 100 cc normal saline within ten minutes as a single dose , is prescribed after the surgery in recovery room.

Category

Treatment - Drugs

2

Description

After transfer the patient to the recovery room and extubation of trachea, and eventually the patient returned to full consciousness, with relation to the patient's pain is measured and recorded. Placebo as an intravenous infusion of 100 cc normal saline within ten minutes , is prescribed after the surgery in recovery room.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Chamran Hospital

Full name of responsible person

Hamid Reza Eftekharian

Street address

Shiraz University Of Medical Sciences, Shiraz Chamran Hospital, Chamran Blvd., Shiraz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shiraz University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Hatam

Street address

Vice-Chancellery of Research and Technology, Shiraz University of Medical Sciences, Zand Avenue.

City

Shiraz

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, Shiraz University 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

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Hamid Reza Eftekharian

Position

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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