Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A Clinical trial of paracetamole 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-opoid 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 analoug 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 analog scale100-mm, were evaluated. Pain was measured 12 hours after injection of paracetamol and using opoids 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, gasterointestinal 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

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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 paracetamole 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 salin 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 salin 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

City
Shiraz

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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Full name of responsible person
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Assistant professor

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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