Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of systemic perioperative lidocaine infusion during bimaxillary surgery for post-operative recovery management: A Clinical Randomized Trial.

Protocol summary

Summary

(1)Objectives: Lidocaine, is the first amino amide-type of local anesthetics, and have analgesic, antihyperalgesic, and antiinflammatory effects. These properties are mediated by a variety of mechanisms, including sodium channel blockade, as well as inhibition of G protein–coupled receptors and N- methyl- D- aspartate receptors. Inhibition of Postoperative Pain by Continuous Low- Dose intravenous Infusion of Lidocaine is devoid of side effects and can be used to decrease the severity of postoperative pain, therefore this study aims to reducing the need for potent morphinomimetic drugs in the postoperative period to reduce pain after surgery will be performed. Also, lidocaine can reduce side effects such as nausea and vomiting, postoperative shivering and be effective in reducing intraoperative bleeding. (2) Design: A total of 60 adult patients aged 16 to 40 years will be randomly admitted to the chamran hospital requiring bimaxillary orthognathic surgery had studied. The following parameters such as: Individual patient information , medical history, the patient's hemodynamic values before- during and after surgery, duration of operation, the amount of blood loss during operation and blood products transfusion, the use of drugs or narcotics for pain relief , postoperative nausea and vomiting and postoperative shivering will be recorded. (3) Setting and conduct: The patients were randomly divided to receive either lidocaine (group I) or saline (group II) is allocated, while anesthesiologist, nurses and patients are unaware of the content of injection (Medications prepared by other nurses and are randomly coded) (4) Participants including major eligibility criteria: Patients with no history of systemic disease and without taking any analgesic medications criteria that were willing to cooperate in this study were enrolled; and Exclusion criteria included known allergy to the study drugs; Serious adverse drug reaction to amide local anaesthetics; hepatic and renal dysfunction ; patients with heart block including second or third degree (without pacemaker) ; Severe sinoatrial block (without pacemaker) ; Use of opioid or analgesics 3 days before the study; Acute Porphyria; Accelerated idioventricular rhythm ; Bradycardia ; and Patients who did not sign the informed consent. (5) Intervention: Patients in the first group will be received an intravenous "Lidocaine" 1 mg / kg body weight bolus for 5 min followed by 2 mg / kg / hr dissolved in saline via pump infusion and the second group will receive " placebo" as same bolus volume of "normal salin" in a 5-minute intravenous infusion and is continued until the en of operation. (6) main outcome measures: During surgery the patient's heart rate, blood pressure and blood oxygen saturation is recorded at specified intervals and at the end of the operation will take analgesics were recorded. After surgery the patients were monitored for up to 4 hours in the recovery room and pain intensity (VAS) is measured by a person who was unaware of group members every half hour, also duration of operation, the amount of blood loss during operation and blood products transfusion, the use of drugs or narcotics for pain relief , postoperative nausea and vomiting and postoperative shivering will be recorded. In the surgical ward for 12 hours, if the drug is administered by a nurse for pain relief will be recorded. And then any post-operative complications will be asked in the questionnaire .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201308141674N8**
Registration date: **2013-09-04, 1392/06/13**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date
2013-09-04, 1392/06/13

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
2013-09-23, 1392/07/01
Expected recruitment end date
2014-10-22, 1393/07/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of systemic perioperative lidocaine infusion during bimaxillary surgery for post-operative recovery management: A Clinical Randomized Trial.

Public title
Perioperative Continuous Intravenous Lidocaine Infusion For Evaluation Of Postoperative Recovery Profile In Orthognathic Surgery.
Purpose
Prevention
Inclusion/Exclusion criteria
Patients with no history of systemic disease and without taking any analgesic medications criteria that were willing to cooperate in this study were enrolled; and Exclusion criteria included known allergy to the study drugs; Serious adverse drug reaction to amide local anaesthetics; hepatic and renal dysfunction ; patients with heart block including second or third degree (without pacemaker) ; Severe sinoatrial block (without pacemaker) ; Use of opioid or analgesics 3 days before the study; Acute Porphyria; Accelerated idioventricular rhythm ; Bradycardia ; and Patients who did not sign the informed consent.
Age
From **16 years** old to **40 years** old
Gender
Both

Phase
2
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
Ethics committee Of Shiraz University Of Medical Sciences
Street address
Shiraz University of Medical Sciences , Vice-Chancellery of Research and Technology, Zand Avenue, Shiraz
City
Shiraz
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197871345
Approval date
2013-09-20, 1392/06/29
Ethics committee reference number
CT-P-92-6338

Health conditions studied

1

Description of health condition studied
Bimaxillary orthognathic surgery
ICD-10 code
00
ICD-10 code description
00

Primary outcomes

1

Description
Heart rate and blood pressure monitoring
Timepoint
During operation and end of surgery
Method of measurement
Heart rate and blood pressure measuring device

2

Description
The severity of postoperative pain
Timepoint
In the recovery room
Method of measurement
Visual analog scale

3

Description
The amount of intraoperative bleeding
Timepoint
During surgery and in the recovery room
Method of measurement
Cc in volume suction and Surgical gauze counting

Secondary outcomes

1

Description
Use of intraoperative blood products
Timepoint
end of operation
Method of measurement
Volume used

2

Description
Side effects of lidocaine
Timepoint
In the recovery room and the End of operation
Method of measurement
Questionnaire

3

Description
Dosage of of narcotic drugs or analgesics in ward surgery
Timepoint
In the recovery room and the End of operation
Method of measurement
Visual analog scale

4

Description
Urine volume
Timepoint
During surgery and in the recovery room
Method of measurement
Cc per patient body weight per hour

5

Description
Postoperative shivering
Timepoint
In the recovery room
Method of measurement
Observation of the patient

6

Description
Nausea and vomiting after surgery
Timepoint
In the recovery room and the End of operation
Method of measurement
Observation of the patient

7

Description
Agitation after anesthesia
Timepoint
In the recovery room and the End of operation
Method of measurement
Observation of the patient

8

Description
Dosage of of narcotic drugs or analgesics in ward surgery
Timepoint
In the ward surgery after 12 hr.
Method of measurement
Questionnaire

Intervention groups

1

Description
Patients in the first group will be received "Lidocaine" an initial dose of 1 mg / kg body weight intravenously during 5 minutes and then continuously Lidocaine 2 mg / kg / hr via pump infusion until the end of operation.
Category
Treatment - Drugs

2

Description
The placebo group (Normal saline) will be given an initial dose of the same volume of nomal saline intravenously and infusion of normal saline continued until end of surgery.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shiraz Chamran Hospital
Full name of responsible person
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City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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

Full name of responsible person

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Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-Chancellery of Research and Technology, 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

Shiraz Chamran Hospital

Full name of responsible person

Arash Karami

Position

Resident of Oral and Maxillofacial Surgery Departement

Other areas of specialty/work

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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