Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The investigating the effect of preoperative diclofenac suppository on opioid consumptiom and nausea and vomiting in maxillofacial surgeries

Protocol summary

Study aim
Investigating the effect of preoperative diclofenac suppository on opioid consumption and nausea and vomiting in maxillofacial surgeries

Design
Clinical trial with control group, with parallel group, double blind, randomized, phase 3 on 60 patient. Randomization was done using random number table.

Settings and conduct
setteing: Maxillofacial surgery patients in Shahid Rahnemon hospital operation room, conduct: Prescribtion of Diclofenac and Glycerin suppository with randomization. Researcher and patients blinded with randomized prescription of drugs and placebo using random number table by a third person.

Participants/Inclusion and exclusion criteria
inclusion criteria: intermaxillary fixation (IMF) required for patients after maxillofacial surgeries. Exclusion criteria: addiction heart, liver, kidney and gasterointestinal disease coaglupathy problemes pregnancy

Intervention groups
Intervention group: prescribe Diclofenac suppository
Control group: prescribe Glycerin suppository

Main outcome variables
Nausea, Vomiting, Opioid consumption dosage

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200606047664N1**
Registration date: **2020-07-12, 1399/04/22**
Registration timing: **retrospective**

Last update: **2020-07-12, 1399/04/22**
Update count: **0**

Registration date
2020-07-12, 1399/04/22

Registrant information

Name
seyed mojtaba alavikia

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 35 3624 7450

Email address
sm.alavikia@spu.ssu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-08-23, 1398/06/01

Expected recruitment end date
2020-02-20, 1398/12/01

Actual recruitment start date
2019-08-23, 1398/06/01

Actual recruitment end date
2020-02-20, 1398/12/01

Trial completion date
2020-02-22, 1398/12/03

Scientific title
The investigating the effect of preoperative diclofenac suppository on opioid consumptiom and nausea and vomiting in maxillofacial surgeries

Public title
Investigating the effect of diclofenac suppository on nausea and vomiting

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients required IMF post maxillofacial surgeries

Exclusion criteria:
pregnancy coaglupathy disfunction heart, liver, kidney and gasterointestinal disease history addiction history

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization, Personal randomization, Randomized number table, Third person for concealment

Blinding (investigator's opinion)
Double blinded

Blinding description
Researcher name 30 question sheet "A" and 30 question sheet "B", "A and B" show Diclofenac suppository and Glycerin suppository that only research observer knows. Each patient before operation choose one of the question sheet randomly and refer to one of the groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Yazd University of Medical Sciences

Street address
Yazd University of Medical Sciences, Shahid Sadoughi Blvd, Bahonar Square

City
Yazd

Province
Yazd

Postal code
۸۹۱۶۹۷۸۴۷۷

Approval date
2020-02-22, 1398/12/03

Ethics committee reference number
IR.SSU.REC.1398.228

Health conditions studied

1

Description of health condition studied
Nausea and vomiting

ICD-10 code
R11

ICD-10 code description
Nausea and vomiting

Primary outcomes

1

Description
Nausea

Timepoint
after recovery, 6 hours post operation, 12 hours post operation

Method of measurement
According to the questionnaire using symptom of nausea.

2

Description
Vomiting

Timepoint
after recovery, 6 hours post operation, 12 hours post operation

Method of measurement
According to the questionnaire using sign of vomiting.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Diclofenac suppository 100 mg preoperation and Diclofenac suppository 50 mg postoperation

Category
Treatment - Drugs

2

Description
Control group: Glycerin suppository 100 mg preoperation and Glycerin suppository 50 mg postoperation

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Rahnemon hospital
Full name of responsible person
Alireza Navvab azam
Street address
Shahid Rahnemon hospital, Farokhi Ave
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Email
Rahnemoonhospital@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Masoud Mirzaie
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Yazd University of Medical Sciences, Shahid Sadoughi Blvd, Bahonar Square
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Email
yazd.ircme@ssu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd University of Medical Sciences
Proportion provided by this source
80
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Seyed mojtaba Alavikia
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available