

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### The investigating the effect of preoperative diclofenac suppository on opioid consumption 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

setting: Maxillofacial surgery patients in Shahid Rahnemon hospital operation room, conduct: Prescription 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 gastrointestinal disease coagulopathy problems 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 consumption 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 coagulopathy dysfunction heart, liver, kidney and gastrointestinal 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

**City**

Yazd

**Province**

Yazd

**Postal code**

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**Phone**

+98 35 3312 2001

**Email**

Rahnemohospital@ssu.ac.ir

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

**Street address**

Blvd imam jafar sadegh

**City**

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**Fax****Email**

sm.alavikia@spu.ssu.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Masoud Mirzaie

**Street address**

Yazd University of Medical Sciences, Shahid Sadoughi

Blvd, Bahonar Square

**City**

Yazd

**Province**

Yazd

**Postal code**

۸۹۱۶۹۷۸۴۷۷

**Phone**

+98 35 3725 8474

**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****Person responsible for scientific 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****Contact****Name of organization / entity**

Yazd University of Medical Sciences

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Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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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