# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 2026

## Evaluating the preemptive effect of metoclopramide and aminophylline on pain after deep vitrectomy

### Protocol summary

**Study aim**
Comparison of aminophylline with metoclopramide on reducing pain intensity after deep vitrectomy

**Design**
This study is a randomized clinical trial with the control group, with parallel groups, double-blinded, phase 3 conducted on 105 patients randomized with random allocation software.

**Settings and conduct**
Participants selected randomly using random allocation software will be divided into groups receiving metoclopramide, aminophylline, or placebo. After surgery, each group receives medication or a placebo, and then vital signs and postoperative pain will be checked at different times. Participants and clinicians will be blind to study groups.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Patients undergoing pars plana deep vitrectomy (20G) surgery, Age between 18 to 75 years, Status classification I or II according to the American Society of Anesthesiologists (ASA) Status Classification System, body mass index (BMI) less than 35, ability to speak, written informed consent Exclusion criteria: History of taking corticosteroids and immunosuppressants since one month before surgery, history of allergies to metoclopramide or aminophylline, taking metoclopramide, aminophylline, or any other analgesics 24 or less than 24 hours before surgery, history of malignancy, uncontrolled diabetes, smoking cigarettes, addictive drugs, and alcohol abuse, chronic pain for more than six months, mental illness, evident preoperative anxiety or tachycardia, history of taking anti-anxiety or anti-arrhythmic medications, history of general anesthesia, by using volatile anesthetics, in the last six months

**Intervention groups**
Patients in the first group will receive 0.1 mg/kg of metoclopramide, and the second group will receive 4 mg/kg intravenous aminophylline. The placebo group will receive 10 ml of normal saline solution.

**Main outcome variables**
The intensity of pain based on the VAS scale

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20170716035104N5**
Registration date: **2021-10-27, 1400/08/05**
Registration timing: **retrospective**

Last update: **2021-10-27, 1400/08/05**
Update count: **0**

**Registration date**
2021-10-27, 1400/08/05

**Registrant information**

**Name**
Roham Nik Khah

**Name of organization / entity**
Medical University of Isfahan

**Country**
Iran (Islamic Republic of)

**Phone**
+98 31 3668 6444

**Email address**
admin.ycc@med.mui.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2017-05-25, 1396/03/04

**Expected recruitment end date**
2018-03-20, 1396/12/29

**Actual recruitment start date**
2017-05-25, 1396/03/04

**Actual recruitment end date**
2018-03-20, 1396/12/29
**Trial completion date**
2018-03-20, 1396/12/29

**Scientific title**
Evaluating the preemptive effect of metoclopramide and aminophylline on pain after deep vitrectomy

**Public title**
Aminophylline and metoclopramide in pain after vitrectomy
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Patients undergoing pars plana deep vitrectomy (20G) surgery Age between 18 to 75 years Status classification I or II according to the American Society of Anesthesiologists (ASA) Status Classification System Body mass index (BMI) less than 35 Ability to speak Written informed consent
**Exclusion criteria:**
History of taking corticosteroids and immunosuppressants since one month before surgery History of allergies to metoclopramide or aminophylline, Taking metoclopramide, aminophylline, or any other analgesics 24 or less than 24 hours before surgery, History of malignancy, uncontrolled diabetes, smoking cigarettes, addictive drugs, and alcohol abuse, chronic pain for more than six months, mental illness, evident preoperative anxiety or tachycardia, history of taking anti-anxiety or anti-arrhythmic medications, and a history of general anesthesia by using volatile anesthetics, in the last six months
**Age**
From **18 years** old to **75 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Participant
- Care provider

**Sample size**
Target sample size: **102**
Actual sample size reached: **105**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
In this study, patients are listed according to referral to surgical centers, arranged from one to 105, respectively. These numbers are then randomly divided into three groups (each will contain 35 cases) by Random Allocation Software (available at: http://ftp.mui.ac.ir/RA.zip). The software is set to generate numbers in a single block, based on numeric and sequential coding with a length of three digits. By hitting the Generate key, numbers from one to 105 are randomly assigned to each of the three groups defined in this study (metoclopramide, aminophylline, and placebo). The output list is copied from the software and will be copied in Microsoft Excel software.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
An anesthesiologist who will be unaware of the study methods would prepare the drugs in similar syringes and label them with random numbers to be delivered to the study conductor. Patients will be also unaware of the type of medication they receive.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
The Ethics committee of Esfahan University of Medical Sciences
**Street address**
Isfahan University of Medical Sciences, Hezar Jarib Ave., Esfahan, Iran.
**City**
Esfahan
**Province**
Isfehan
**Postal code**
7346181746
**Approval date**
2017-05-22, 1396/03/01
**Ethics committee reference number**
IR.MUI.REC.1396.3.217

## Health conditions studied

### 1

**Description of health condition studied**
Pain intensity after deep vitrectomy
**ICD-10 code**
Z98.89
**ICD-10 code description**
Other specified postprocedural states

## Primary outcomes

### 1

**Description**
Patient's post-operative pain intensity
**Timepoint**
At the beginning of admission at the recovery ward, then at 30 and 60 minutes and 2, 4, 8, 16, and 24 hours after

entering the recovery ward.

**Method of measurement**

The Visual Analog Scale (VAS)

## Secondary outcomes

### 1

**Description**

Mean of blood pressure (mm Hg)

**Timepoint**

During surgery (once), in the recovery ward, and 8 hours after the surgery

**Method of measurement**

Clinical mercury manometer

### 2

**Description**

Heart rate (beats per minute)

**Timepoint**

During surgery (once), in the recovery ward, and 8 hours after the surgery

**Method of measurement**

Beat count by palpating distal radius pulse

### 3

**Description**

Respiratory rate (breaths per minute)

**Timepoint**

During surgery (once), in the recovery ward, and 8 hours after the surgery

**Method of measurement**

Capnometry

### 4

**Description**

Pethidine required for sedation

**Timepoint**

Whenever the visual analog scale scores more than 3

**Method of measurement**

It is measured by counting the number of pethidine injections up to the end of 24 hours after admission to the recovery ward

### 5

**Description**

The patients' satisfaction status

**Timepoint**

Until the end of 24 hours after entering the recovery ward

**Method of measurement**

Questionnaire (completely satisfied, relatively satisfied, relatively dissatisfied, and completely dissatisfied)

### 6

**Description**

Recovery time

**Timepoint**

Until the end of 24 hours after entering the recovery ward

**Method of measurement**

Timer

## Intervention groups

### 1

**Description**

The first intervention group will receive 0.1 mg/kg of metoclopramide by intravenous infusion for ten minutes, 15 minutes before the end of surgery.

**Category**

Treatment - Drugs

### 2

**Description**

The second intervention group will receive 4 mg/kg of aminophylline by intravenous infusion for ten minutes, 15 minutes before the end of surgery.

**Category**

Treatment - Drugs

### 3

**Description**

Patients in the control (placebo group) will receive 10 ml of intravenous normal saline for ten minutes, 15 minutes before the end of surgery.

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Feiz hospital

**Full name of responsible person**

Dariush Moradi Farsani

**Street address**

Feiz hospital,Modares st, Esfahan

**City**

Esfahan

**Province**

Isfehan

**Postal code**

8174673461

**Phone**

+98 31 3445 2034

**Email**

feiz@mui.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**
Shaghayegh Haghjoo Javanmard

**Street address**
Isfahan University of Medical Sciences, Hezar Jarib Ave., Esfahan

**City**
Esfahan

**Province**
Isfehan

**Postal code**
7346181746

**Phone**
+98 31 3668 8138

**Email**
sh_haghjoo@med.mui.ac.ir

**Grant name**

**Grant code / Reference number**

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

**Title of funding source**
Esfahan University of Medical Sciences

**Proportion provided by this source**
100

**Public or private sector**
Public

**Domestic or foreign origin**
Domestic

**Category of foreign source of funding**
*empty*

**Country of origin**

**Type of organization providing the funding**
Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**
Esfahan University of Medical Sciences

**Full name of responsible person**
Daroush Moradi Farsani

**Position**
Associate professor

**Latest degree**
Specialist

**Other areas of specialty/work**
Anesthesiology

**Street address**
Isfahan University of Medical Sciences, Hezar Jarib Ave., Esfahan

**City**
Esfahan

**Province**
Isfehan

**Postal code**
7346181746

**Phone**
+98 31 3620 1992

**Email**
dmoradi@med.mui.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Esfahan University of Medical Sciences

**Full name of responsible person**
Daroush Moradi Farsani

**Position**
Associate professor

**Latest degree**
Specialist

**Other areas of specialty/work**
Anesthesiology

**Street address**
Isfahan University of Medical Sciences, Hezar Jarib Ave., Esfahan

**City**
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**Province**
Isfehan

**Postal code**
7346181746

**Phone**
+98 31 3620 1992

**Email**
dmoradi@med.mui.ac.ir

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Esfahan University of Medical Sciences

**Full name of responsible person**
Dariush Moradi Farasni

**Position**
Associate professor

**Latest degree**
Specialist

**Other areas of specialty/work**
Anesthesiology

**Street address**
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**City**
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**Province**
Isfehan

**Postal code**
7346181746

**Phone**
+98 31 3620 1992

**Email**
dmoradi@med.mui.ac.ir

## 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