

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### The effect of premedication with oral acetaminophen on the prevention of localized pain from intravenous injection of propofol as induction agent in patients under general anesthesia

#### Protocol summary

##### Study aim

Evaluation of the effect of premedication with oral acetaminophen on the prevention of localized pain from intravenous injection of propofol

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 150 patients. Six-block method was used for individual randomization.

##### Settings and conduct

For this study, the license of the medical school and the ethics committee of Tehran University of Medical Sciences will be obtained. Data will be collected from 150 patients in the operating room of Shariati Hospital. We have 2 intervention groups with 500 mg and 1000 mg acetaminophen, and a control group with placebo. Patients receive oral medication one hour before entering the operating room. After delivery of a quarter of the calculated dose of propofol, the patient is asked to rate his or her pain at the injection site using VNRS. Both the patient and the pain assessor, are not aware of the type of oral medication. The anesthesiology resident gives the medications to the patients and collects the data recorded by the pain assessor and, before statistical analysis, matches the data with the patients.

##### Participants/Inclusion and exclusion criteria

Age 18 to 60 years; Use of propofol for anesthesia; Absence of liver and kidney disease; Absence of chronic pain in the body; Ability to communicate effectively

##### Intervention groups

The Pb, P500, and P1000 groups receive the drug one hour before transfer to the operating room. Each patient receives 2 placebo tablets (group Pb), 1 placebo tablet and 1 paracetamol 500 mg tablet (group P500) or 2 paracetamol 500 mg tablets (group P1000). Placebo and paracetamol are the same in shape, size, color and weight. None of them will receive painkillers or other sedatives.

#### Main outcome variables

The extent of local pain after intravenous injection of propofol

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210511051268N1**

Registration date: **2021-05-13, 1400/02/23**

Registration timing: **prospective**

Last update: **2021-05-13, 1400/02/23**

Update count: **0**

##### Registration date

2021-05-13, 1400/02/23

##### Registrant information

##### Name

Seyed Mohsen Mousavi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8836 3149

##### Email address

sm.mousavi.md.anesthesiology@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-06-22, 1400/04/01

##### Expected recruitment end date

2021-09-21, 1400/06/30

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of premedication with oral acetaminophen on the prevention of localized pain from intravenous injection of propofol as induction agent in patients under general anesthesia

**Public title**

The effect of acetaminophen on propofol injection pain

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

All patients for whom propofol is used as an induction of anesthesia

**Exclusion criteria:**

Weight less than 50 kg Chronic pain in any area of the body High blood pressure Cardiovascular disease Cerebrovascular disease Difficulty communicating (even if there is a marked drop in level of consciousness with the initial injection dose) Cirrhosis Abnormal liver function test results (AST and ALT more than twice normal) Kidney failure or creatinine clearance greater than 1.2 Allergy to acetaminophen Allergy to propofol Patients in whom propofol is not used to induce anesthesia Those who do not have a venous catheter in the back of the hand Those whose catheter size is not 20G those for whom we have to use rapid sequence induction for their anesthesia

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **150**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Restricted randomization is done using permuted block randomization method, with six blocks. Randomization was performed using the website [www.randomization.com](http://www.randomization.com). The method of concealment is to use opaque envelopes sealed in random sequence.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Both the patient and an independent evaluator (in charge of anesthesia) and the researcher and data analyzer and the outcome evaluator are not aware of the

type of oral medication. Placebo and paracetamol are the same in shape, size, color and weight.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

**Street address**

Enghelab St., Ghods St., Poursina St.

**City**

Tehran

**Province**

Tehran

**Postal code**

1417613151

**Approval date**

2020-09-02, 1399/06/12

**Ethics committee reference number**

IR.TUMS.MEDICINE.REC.1399.383

**Health conditions studied****1****Description of health condition studied**

Local Pain due to intravenous injection of propofol

**ICD-10 code**

M79.643

**ICD-10 code description**

Pain in unspecified hand

**Primary outcomes****1****Description**

11-point verbal numerical rating score (VNRS) for pain caused by propofol injection

**Timepoint**

Measuring the amount of pain right after injecting a quarter of the induction dose

**Method of measurement**

11-Point Verbal Numerical Ranking (VNRS)

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

Intervention group: P500 group (patients with 500 mg of oral paracetamol) will receive medication 1 hour before transfer to the operating room. Each patient receives 1 placebo tablet and 1 paracetamol 500 mg tablet. (Because in the other intervention group, patients take 2 acetaminophen pills, so here they take one medicine pill and one placebo pill) None of them will receive any other analgesic or sedative. Aria 500 mg acetaminophen tablet is a product of Aria Pharmaceutical Company. Immediately after injecting a quarter of the propofol induction dose, the patient's local pain at the injection site is assessed by the VNRS numerical criterion and the patient scores from 0 to 10.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: The placebo group receives the drug 1 hour before transfer to the operating room. Each patient receives 2 placebo tablets. (Because in one intervention group, patients take 2 acetaminophen pills, so here they take two placebo pills). None of them will receive any other analgesic or sedative. Immediately after injecting a quarter of the propofol induction dose, the patient's local pain at the injection site is assessed by the VNRS numerical criterion and the patient scores from 0 to 10.

#### Category

Placebo

### 3

#### Description

Intervention group: Intervention group: P1000 group (patients with 1000 mg of oral paracetamol) receive medication 1 hour before transfer to the operating room. Each patient receives 2 tablets of 500 mg paracetamol. None of them will receive any other analgesic or sedative. Aria 500 mg acetaminophen tablet is a product of Aria Pharmaceutical Company. Immediately after injecting a quarter of the propofol induction dose, the patient's local pain at the injection site is assessed by the VNRS numerical criterion and the patient scores from 0 to 10.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Operating room of Shariati Hospital in Tehran

##### Full name of responsible person

Alireza Saliminia

#### Street address

alal Al-Ahmad Highway, not far from Kargar, Shariati Hospital, first floor, operating room

#### City

Tehran

#### Province

Tehran

#### Postal code

1411713135

#### Phone

+98 21 8490 1000

#### Email

shariatihosp@tums.ac.ir

#### Web page address

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Dr. Mohammad Ali Sahraeian

##### Street address

Keshavarz Boulevard, corner of Quds Street, Central University Organization, sixth floor, Vice Chancellor for Research and Technology

##### City

Tehran

##### Province

Tehran

##### Postal code

1417935840

##### Phone

+98 21 8836 3149

##### Email

vcr@tums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Tehran 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

Tehran University of Medical Sciences

**Full name of responsible person**

Seyed Mohsen Mousavi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

Tehran / Shahrak-e-Gharb / Dadman Blvd. / Sepehr St.  
/ No. 117 / Unit 6

**City**

Tehran

**Province**

Tehran

**Postal code**

1468734117

**Phone**

+98 21 8836 3149

**Email**

sm.mousavi.md.anesthesiology@gmail.com

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

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

Tehran University of Medical Sciences

**Full name of responsible person**

Seyed Mohsen Mousavi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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+98 21 8836 3149

**Email**

sm.mousavi.md.anesthesiology@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Seyed Mohsen Mousavi

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is 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

**Title and more details about the data/document**

All data is potentially shareable after unidentified individuals

**When the data will become available and for how long**

Access period starts 6 months after the results are published

**To whom data/document is available**

Access is free for everyone

**Under which criteria data/document could be used**

Access is free for everyone

**From where data/document is obtainable**

Person in charge of the project / Seyed Mohsen Mousavi  
sm.mousavi.md.anesthesiology@gmail.com

**What processes are involved for a request to access data/document**

Immediately after contacting the project manager

**Comments**