

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the Effect of intravenous Acetaminophen and oral Acetaminophen in the Prevention of Delirium in the Elderly After Heart Surgery

#### Protocol summary

##### Study aim

Comparison of the effect of intravenous acetaminophen and oral acetaminophen in the prevention of delirium in the elderly after heart surgery

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 64 patients. Random Allocation Software was used for randomization

##### Settings and conduct

Patients undergoing heart surgery referred to Fatemeh Zahra Hospital in Sari, both blind, in which the researcher, patient, nurse, injector and analyzer are blinded and receive the drug in sealed envelopes

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who are at least 60 years old and undergo heart surgery Exclusion criteria: preoperative ventricular ejection fraction less than 30%, emergency procedure, aortic dissection surgery, pre-existing cognitive dysfunction, Parkinson's disease, Alzheimer's disease, recent seizures (less than 3 months), use of prophylactic drugs to reduce Cognitively, serum creatinine is more than 2 mg / dL, liver dysfunction (liver enzymes more than four times the base), alcohol or drug abuse (more than 10 drinks per week), sensitivity to any of the drugs studied

##### Intervention groups

Groups are divided into groups A (intravenous acetaminophen), B (oral acetaminophen). Patients in group A are given 1 gram of intravenous acetaminophen within one hour after hospitalization in the ICU and every 8 hours after surgery and continue until the first 48 hours after surgery. A total of 6 doses are given. Have 500 mg of oral acetaminophen every 6 hours for 48 hours for a total of 8 postoperative doses. Both groups also receive painkillers (morphine). Oral placebo 500 mg every 6 hours used in this study and intravenous placebo is the same as normal saline 0.9% used every 8 hours for the

patient

##### Main outcome variables

Delirium prevention, pain control

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211010052718N1**

Registration date: **2021-11-20, 1400/08/29**

Registration timing: **retrospective**

Last update: **2021-11-20, 1400/08/29**

Update count: **0**

##### Registration date

2021-11-20, 1400/08/29

##### Registrant information

##### Name

alireza nikzad

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3326 3539

##### Email address

a.nikzad@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-02-29, 1398/12/10

##### Expected recruitment end date

2020-08-10, 1399/05/20

##### Actual recruitment start date

2020-02-29, 1398/12/10

**Actual recruitment end date**

2021-08-21, 1400/05/30

**Trial completion date**

2021-08-21, 1400/05/30

**Scientific title**

Comparison of the Effect of intravenous Acetaminophen and oral Acetaminophen in the Prevention of Delirium in the Elderly After Heart Surgery

**Public title**

Comparison of the effect of intravenous and oral acetaminophen in the prevention of delirium

**Purpose**

Treatment

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

Patients who are at least 60 years old and undergo heart surgery

**Exclusion criteria:**

Preoperative ventricular ejection fraction less than 30%  
Emergency method Aortic dissection surgery  
Pre-existing cognitive dysfunction  
Parkinson's disease  
Alzheimer's disease  
Recent seizures (less than 3 months), taking prophylactic medications for cognitive decline  
Serum creatinine greater than 2 mg / dL  
Liver dysfunction (liver enzymes more than four times basal)  
Alcohol or drug abuse (more than 10 drinks per week)  
Allergy to any of the studied drugs

**Age**

From **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: **64**

Actual sample size reached: **64**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The random assignment process will be assigned to two groups in blocks. A and B are 16 blocks of 4 and the Random Allocation software is used. The drugs are similar in appearance and volume and are responsible for preparation. The tablets for each group, which are similar in appearance, were prepared in another room and delivered to the person in charge in the operating room. Taber was injected into the patient according to the randomization block and random letters A and B without knowing the type of drug.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The injecting nurse and the patient in charge of data

collection are kept blind due to the fact that the drugs have a similar appearance and are prepared in another room and delivered to the nurse in sealed envelopes for bilateral blinding of patients into two groups of 32 people. Divided, one hour after admission to the ICU of the first group (A) 1 gram of intravenous acetaminophen and oral placebo to the second group (B) 500 mg of oral acetaminophen and 1 gram of intravenous placebo is administered. They do not have two groups

**Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Ethics Committee of Mazandaran University of Medical Sciences, Imam Khomeini Medical Center

**Street address**

Amir Mazandarani Blvd. Imam Khomeini Educational and Medical Center

**City**

Sari

**Province**

Mazandaran

**Postal code**

33131 - 48166

**Approval date**

2020-02-19, 1398/11/30

**Ethics committee reference number**

IR.MAZUMS.IMAMHOSPITAL.REC.1399.006

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

Prevention of delirium in the elderly after heart surgery

**ICD-10 code**

F05

**ICD-10 code description**

Delirium due to known physiological condition

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

Delirium after surgery

**Timepoint**

The first 48 hours after surgery continue

**Method of measurement**

Visual Analogue Scale

## Secondary outcomes

### 1

#### Description

The length of stay in the intensive care unit and hospital

#### Timepoint

After clearance

#### Method of measurement

Hospital file

## Intervention groups

### 1

#### Description

Intervention group: Intravenous acetaminophen 1 g of Galenus's product is given within one hour after ICU admission and every 8 hours after surgery and continues until the first 48 hours after surgery.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: Oral acetaminophen 500 mg of Galenus every 6 hours for 48 hours for a total of 8 postoperative doses

#### Category

Treatment - Drugs

### 3

#### Description

Control group: Intravenous placebo 1 g of the product of Shahid Ghazi Pharmaceutical Company is given within one hour after hospitalization in the ICU and every 8 hours after the operation and continues until the first 48 hours after the operation.

#### Category

Placebo

### 4

#### Description

Control group: Placebo 500 mg of Merck's product is given every 6 hours for 48 hours for a total of 8 doses after surgery.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini Medical Center

##### Full name of responsible person

Javad Taziki

##### Street address

Amir Mazandarani Blvd.

##### City

Sari

##### Province

Mazandaran

##### Postal code

33131 - 48166

##### Phone

+98 11 3336 1700

##### Fax

+98 11 3336 1700

##### Email

javadtazikii@gmail.com

##### Web page address

<http://mazums.ac.ir>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Majid Saedi

##### Street address

Moalem Ave

##### City

Sari

##### Province

Mazandaran

##### Postal code

48157-33971

##### Phone

+98 11 3325 7230

##### Fax

+98 11 3325 7230

##### Email

m.saedi@mazums.ac.ir

##### Web page address

<https://www.mazums.ac.ir>

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Mazandaran 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**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Javad Taziki

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

Amir Mazandarani Blvd.

**City**

Sari

**Province**

Mazandaran

**Postal code**

33131 - 48166

**Phone**

+98 11 3336 1700

**Fax**

+98 11 3336 1700

**Email**

[javadtazikii@gmail.com](mailto:javadtazikii@gmail.com)

**Web page address**

<http://mazums.ac.ir>

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Javad Taziki

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

Amir Mazandarani Blvd.

**City**

Sari

**Province**

Mazandaran

**Postal code**

33131 - 48166

**Phone**

+98 11 3336 1700

**Fax**

+98 11 3336 1700

**Email**

[javadtazikii@gmail.com](mailto:javadtazikii@gmail.com)

**Web page address**

<http://mazums.ac.ir>

## Person responsible for updating data

### Contact

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Javad Taziki

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

Amir Mazandarani Blvd.

**City**

Sari

**Province**

Mazandaran

**Postal code**

33131 - 48166

**Phone**

+98 11 3336 1700

**Fax**

+98 11 3336 1700

**Email**

[javadtazikii@gmail.com](mailto:javadtazikii@gmail.com)

**Web page address**

<http://mazums.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