Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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alireza nikzad

Name of organization / entity

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Iran (Islamic Republic of)

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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
Delrium 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
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Sponsors / Funding sources

1

Sponsor
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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

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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