Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

The Effect of Ondansetron on Acetaminophen's analgesic power in Cholecystectomy Patients

Protocol summary

Study aim
The Effect of Ondansetron on Acetaminophen's analgesic power

Design
A double-blinded, parallel-group clinical trial with random sampling and allocation in intervention and control group

Settings and conduct
An available double-blinded sampling will be conducted on patients referred to the central operating room of Qaem Hospital, Mashhad. They will be all candidates of Laparoscopic Cholecystectomy surgery with GA. Neither analyst nor participant will be informed about group allocation. At the last 30 minutes of the surgery, In the first intervention group 1000 mg acetaminophen infusion and 4 mg of ondansetron will be injected and In the second intervention group, 1000 mg acetaminophen infusion and 8 mg of ondansetron will be injected. at the last 30 minutes of the surgery In the control group, 1000 mg acetaminophen infusion and 10 mg of metoclopramide will be injected.Checklist variables are recorded (pain, nausea and The postoperative analgesic consumption).

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1 & 2 ASA class, Age of 18-64, Speak Persian Exclusion criteria: addiction, taking analgesic drugs within the last 24 hours, taking ondansetron or metoclopramide within the last 24 hours, chronic pain, history of Drug allergy, history of Psychological disease

Intervention groups
At the last 30 minutes of the surgery, In the first intervention group 1000 mg acetaminophen infusion and 4 mg of ondansetron will be injected and In the second intervention group, 1000 mg acetaminophen infusion and 8 mg of ondansetron will be injected. at the last 30 minutes of the surgery In the control group, 1000 mg acetaminophen infusion and 10 mg of metoclopramide will be injected.

Main outcome variables
Acetaminophen's analgesic effect

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160516027925N4**
Registration date: **2019-07-06, 1398/04/15**
Registration timing: **registered_while_recruiting**

Last update: **2019-07-06, 1398/04/15**
Update count: **0**

Registration date
2019-07-06, 1398/04/15

Registrant information

Name
Amir Zoka

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
2019-06-22, 1398/04/01

Expected recruitment end date
2019-11-21, 1398/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The Effect of Ondansetron on Acetaminophen's analgesic power in Cholecystectomy Patients

Public title
The Effect of Ondansetron on Acetaminophen's analgesic power
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
1 & 2 ASA class Age of 18-64 Being able to speak and understand Persian
Exclusion criteria:
history of Psychological disease history of Ondansetron & Acetaminophen allergy any chronic pain in part's of the body taking ondansetron or metoclopramide within the last 24 hours taking any analgesic drugs within the last 24 hours alcohol & drug addiction
Age
From **18 years** old to **64 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be assigned to the control or intervention group by drawing a random number out of a bag
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants will not be informed about which group they are in. Also, the data analyst will be blind to which group the participants are assigned
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Knowledge and Health City, In the end of Shahid Fakouri Blvd, Mashhad, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2018-12-04, 1397/09/13
Ethics committee reference number
Ir.mums.medical.rec.1397.593

Health conditions studied

1

Description of health condition studied
The Effect of Ondansetron on Acetaminophen's analgesic power in Cholecystectomy Patients
ICD-10 code
Y57.9
ICD-10 code description
Drug or medicament, unspecified

Primary outcomes

1

Description
Acetaminophen's analgesic power
Timepoint
After surgery in recovery, One hour after surgery in recovery, Six hours after surgery in the ward
Method of measurement
Numerical Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: At the last 30 minutes of the surgery,1000 mg acetaminophen infusion and 4 mg of ondansetron will be injected
Category
Prevention

2

Description
Intervention group: At the last 30 minutes of the surgery, 1000 mg acetaminophen infusion and 8 mg of ondansetron will be injected.
Category
Prevention

3

Description

Control group: at the last 30 minutes of the surgery, 1000 mg acetaminophen infusion and 10 mg of metoclopramide will be injected.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Qaem hospital

Full name of responsible person
Mohsen Sabermoghaddam

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Ahmadabad Blvd, Mashhad, Razavi Khorasan Province

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zoka.am69@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr.Saed Eslami

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Knowledge and Health City, In the end of Shahid Fakouri Blvd, Mashhad, Iran

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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

Mashhad 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
Torbate-Heidaria University of Medical Sciences

Full name of responsible person
Amir Zoka

Position
Academic instructor

Latest degree
Master

Other areas of specialty/work
Anesthesiology

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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

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All de-identified individual participant data will be shared. Both of the entire study protocol and informed consent of the participants in the study are shared too.

When the data will become available and for how long

6 months after the publication of the article

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Given the patient's satisfaction to participate in this study, the data should only be used for similar studies

From where data/document is obtainable

Email to the authors Sabermoghaddamm@mums.ac.ir Zokaa1@thums.ac.ir

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

After the email, the request will be made available to the authors to reach the requesting person within a maximum of one month if the conditions are confirmed.

Comments