

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

Country

Iran (Islamic Republic of)

Phone

+98 51 3822 4395

Email address

zokaa921@mums.ac.ir

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

lr.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 medication, 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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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