

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of ondansetron administration on pain reduction after appendectomy surgery

Protocol summary

Study aim

Determining the effect of ondansetron administration before appendectomy surgery on reducing postoperative pain

Design

A clinical trial with a control group, with parallel design, double-blind, randomized, phase 2 on 80 patients.

Settings and conduct

Immediately before premedication, 4 mg/cc 2 of ondansetron is used as an injection in normal saline for the case group, and 2 cc of distilled water in normal saline is injected as a placebo for the control group. Premedication is done using intravenous fentanyl 2 micrograms per kilogram of body weight and midazolam 0.03 mg/kg. Blinding is done in such a way that first the ondansetron and placebo drugs are coded by an informed person so that their nature is unknown to the prescriber. Measuring the effect of the drug on the variables is also done by another person who is not aware of the type of drug used in each patient.

Participants/Inclusion and exclusion criteria

The criteria for inclusion were uncomplicated appendectomies, the absence of disorders such as cardiac, respiratory, liver, and neurological diseases, and the absence of drug addiction, and patients with A.S.A, 1 and 2 are included in the study. Exclusion criteria include complicated appendectomies, drug addiction, mental diseases, and blood pressure less than 90/60 or more than 180/110 that requires medical intervention.

Intervention groups

Immediately before premedication for the case group, 2 mg/cc of ondansetron is used as an injection in normal saline. Premedication is done using intravenous fentanyl 2 micrograms per kilogram of body weight and midazolam 0.03 mg/kg.

Main outcome variables

Determining the effect of ondansetron on pain after appendectomy; nausea; vomiting; sedation; shivering

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230722058883N1**

Registration date: **2023-08-22, 1402/05/31**

Registration timing: **retrospective**

Last update: **2023-08-22, 1402/05/31**

Update count: **0**

Registration date

2023-08-22, 1402/05/31

Registrant information

Name

Alireza Azarboo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 902 175 3418

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2015-03-21, 1394/01/01

Actual recruitment start date

2014-03-21, 1393/01/01

Actual recruitment end date

2015-03-21, 1394/01/01

Trial completion date

2016-03-19, 1394/12/29

Scientific title

The effect of ondansetron administration on pain reduction after appendectomy surgery

Public title

The effect of ondansetron administration on pain reduction

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

patients with appendectomies without complications the absence of disorders such as cardiorespiratory, liver, and neurological diseases the absence of drug addiction patients with A.S.A. 1,2 were included in the study.

Exclusion criteria:

patients with complications after appendectomy drug addiction mental diseases such as bipolar disorder, schizophrenia, and depression patients with blood pressure less than 90/60 or more than 180/110 that require medical intervention.

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **76**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

80 patients are randomized blocked in two groups of 40 according to the table provided (attached table) from the Random Allocation software. The way to do it is that first, ondansetron and placebo are coded by a knowledgeable person so that their nature is unknown to the prescriber. Ondansetron and placebo are provided by a knowledgeable person to a person who is unaware of the nature of the codes, and they are prescribed by the same person. It is done by an uninformed person, measuring the effect of the drug on the variables is also done by another person who is not aware of the type of drug used in each patient.

Blinding (investigator's opinion)

Double blinded

Blinding description

Double-blinding means that neither the study subjects nor the observers (researchers) know who is in which group. The way to do it is to first code the ondansetron drug and the placebo by a knowledgeable person so that their nature for The prescribing person is unknown. Ondansetron and placebo are presented by a person who is aware of the nature of the codes to a person who is unaware of the nature of the codes, and their prescription is done by the same person who is unaware, and the effect of the drug on the variables is measured by another person who knows the type of drug used in

each patient. It is not aware.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Hormozgan University of Medical Sciences and Healthcare Services

Street address

Poursina St.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2015-03-21, 1394/01/01

Ethics committee reference number

IR.HUMS.REC.1394.056

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

Reduction of post-surgical pain

ICD-10 code

K35

ICD-10 code description

Acute appendicitis

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

According to the visual analog scale (VAS) pain scale, how much pain reduction was experienced in the case group compared to the controls

Timepoint

Before appendectomy and after

Method of measurement

visual analog scale (VAS) pain

Secondary outcomes

empty

Intervention groups

1

Description

In the operating room, standard patient monitoring including EKG, pulse oximetry, blood pressure every 5 minutes, capnography and the patient's initial symptoms are recorded. Immediately before premedication for the group under study, 2 mg/cc of ondansetron is used as an injection in normal saline.

Category

Rehabilitation

2

Description

For the control group, cc2 of distilled water in normal saline is injected as a placebo. Premedication is done using intravenous fentanyl 2 micrograms per kilogram of body weight and midazolam 0.03 mg/kg.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomeini hospital

Full name of responsible person

Peyman Mirghader

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Poursina st.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Grant name

Medical Ethics Committee of Bandar Abbas University of Medical Sciences

Grant code / Reference number

IR.HUMS.REC.1394.056

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

1

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

Peyman Mirghaderi

Position

Consultant

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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Person responsible for updating data

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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