Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Iran (Islamic Republic of)

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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 committe 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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Sponsors / Funding sources

1

Sponsor
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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
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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