

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Formulation of Fast-Dissolving Sublingual Films of ondansetron Succinate by Electrospinning method and physicochemical and clinical evaluation in eye surgery patients

Protocol summary

Study aim

Formulation of Fast-Dissolving Sublingual Films of ondansetron Succinate by Electrospinning method and physicochemical and clinical evaluation in eye surgery patients

Design

A randomized, double-blind, Control and intervention groups clinical trial

Settings and conduct

In this study, first the ondansetron films were made in Kermanshah School of Pharmacy and then this formulation and marketed form are given to patients in Imam Khomeini Hospital Eye Surgery in Kermanshah. Patients are randomly divided into two groups, and the nurse and patient are blinded to this study as the patients are coded and do not know which medication they were taking.

Participants/Inclusion and exclusion criteria

The age range of patients is between 20 and 50 years. Excluded from the study in case of pregnancy and lactation. Patients should not have systemic diseases such as heart, kidney disease. Patients should not take anti-nausea medications until one day before surgery. Do not have a history of allergy to the drug and its components.

Intervention groups

In this study the efficacy and anti-nausea effect of ondansetron sublingual film is compared with the available forms in the market.

Main outcome variables

Nausea: An unpleasant feeling associated with awareness of the need for vomiting. Retching : Respiratory muscle contraction without gastric contents. Vomiting: Muscle contraction and gastric contents are told.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180120038450N2**

Registration date: **2019-08-17, 1398/05/26**

Registration timing: **prospective**

Last update: **2019-08-17, 1398/05/26**

Update count: **0**

Registration date

2019-08-17, 1398/05/26

Registrant information

Name

Shahla Mirzaeei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3824 0526

Email address

shahlamirzaeei@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-22, 1398/05/31

Expected recruitment end date

2019-10-22, 1398/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Formulation of Fast-Dissolving Sublingual Films of ondansetron Succinate by Electrospinning method and physicochemical and clinical evaluation in eye surgery patients

Public title

Evaluation of the Effect of Fast-Dissolving Sublingual Films of ondansetron on the Control of Nausea and Vomiting after Eye Surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Signature of written consent for participation in the study
Age between 20 and 50 years From the point of view of classification of physical condition the American Society of Anesthesiologists was in the 1st and 2nd position

Exclusion criteria:

Pregnancy, breastfeeding Taking drugs with anti-nausea effect in 24 hours before surgery History of motion sickness The history of systemic diseases: heart, kidney, liver, lung, psychosis, diabetes Nausea and vomiting within 24 hours before of eye surgery Use of steroids 24 hours before surgery

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is simple and the unit is individual. The random number table is used as a randomization tool. Creating a random sequence is based on a single sequence of random assignments. The encryption is also done using a random-coded encoded box.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind study, both participants and evaluators of the outcome were unaware of the allocation of study groups. That is, the drugs in each group are similar in appearance.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences and Health Services

Street address

Shahid Beheshti Blvd.- Central Organization of Kermanshah University of Medical Sciences

City

kermanshah

Province

Kermanshah

Postal code

6714858743

Approval date

2019-04-23, 1398/02/03

Ethics committee reference number

IR.KUMS.REC.1398.109

Health conditions studied

1

Description of health condition studied

Patients candidate for eye surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The amount of nausea and vomiting

Timepoint

Baseline (immediately after surgery and before drug administration) and 1, 2, 4, 6 hours after drug administration

Method of measurement

Questionnaire with visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study, we use ondansetron, which is made as a sublingual film with polyvinyl alcohol and beta-cyclodextrin polymers. Films containing 4 mg ondansetron are given sublingually only once after surgery if nausea and vomiting occur.

Category

Treatment - Drugs

2

Description

Control group: Patients in the control group are given ondansetron sublingual tablets at a dose of 4 mg only once in case of nausea. The patient places the drug under his tongue. This form of medicine is produced by Pars Darou Company.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Farid daneshgar

Street address

Islamic Republic Blvd

City

Kermanshah

Province

Kermanshah

Postal code

6718743161

Phone

+98 83 3728 3602

Fax

+98 83 3722 4516

Email

ihosp@kums.ac.ir

Web page address

<https://imamkhomaini.kums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

mirzaeei

Street address

Kermanshah University of medical sciences,
Kermanshah

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Kermanshah

Postal code

6715847141

Phone

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Email

daftarriyat@kums.ac.ir

Web page address

<https://www.kums.ac.ir/>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Shahla Mirzaeei

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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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