

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Study of the effect of chewing gum on the severity of nausea and vomiting after hysteroscopic procedures

Protocol summary

Study aim

Determining the effect of chewing gum on the severity of nausea and vomiting after hysteroscopic procedures

Design

Clinical trial with control group, parallel groups, single-blind, randomized with 52 patients

Settings and conduct

Participants are patients undergoing hysteroscopic surgery at Rasoul Akram and Firoozgar Hospitals. Participants will be randomly assigned to two groups. Outcome assessors will also not be aware of the type of intervention.

Participants/Inclusion and exclusion criteria

Enough teeth to chew gum; ASA 1-3; no phenylketonuria

Intervention groups

Intervention group: chewing gum without flavor. Control group: Endosteron in the amount of 4 mg intravenously.

Main outcome variables

Nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190929044924N2**
Registration date: **2020-07-07, 1399/04/17**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-07, 1399/04/17**

Update count: **0**

Registration date

2020-07-07, 1399/04/17

Registrant information

Name

Reza Farahmandrad

Name of organization / entity

Iran University Of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 8852 2083

Email address

farahmandrad.r@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2021-06-22, 1400/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of chewing gum on the severity of nausea and vomiting after hysteroscopic procedures

Public title

Chew gum on the severity of nausea and vomiting

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Enough teeth to chew gum ASA 1-3 No phenylketonuria

Exclusion criteria:

No history of neuromuscular problems smoking Post operative nausea-vomitin (PONV)

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: 52

Randomization (investigator's opinion)

Randomized

Randomization description

The patients were randomly divided into intervention and control groups using a lottery method. As the names of all participants are placed inside the container. The names are drawn out from the container, respectively, and placed in the intervention and control groups. At the end, the papers containing the names are opened and different groups are determined.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and outcome assessors will not be aware of the type of intervention

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Iran University of Medical Sciences

Street address

Next to Milad Tower, Hemat Highway ,Tehran

City

Tehran

Province

Tehran

Postal code

14496-14535

Approval date

2020-02-29, 1398/12/10

Ethics committee reference number

IR.IUMS.FMD.REC.1398.526

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

Nausea and vomiting

ICD-10 code

R11.2

ICD-10 code description

Nausea with vomiting, unspecified

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

Nausea and vomiting

Timepoint

15 minutes after starting treatment

Method of measurement

Ask the patient

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Participants are asked to continue chewing gum without flavor for at least 10 minutes. The chewing gum used will be the non-essence chewing gum of the FALIM Turkey Company.

Category

Treatment - Surgery

2**Description**

Control group: Endosterone will be injected intravenously at a dose of 4 mg. Endosteron is produced by "Alborz daro" company of Iran.

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Rasoul Akram hospital

Full name of responsible person

Reza Farahmand Rad

Street address

Hazrate Rasoole Akram Hospital, Niayesh St, Satarkhan Av,

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 6435 1444

Email

farahmandrad.r@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyad Abbas Motavalian

Street address

Hemat Highway next to Milad Tower

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2503

Email

amotevalian@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Reza Farahmandrad

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Rasool Akram hospital, Maziar Mansory Ave,
Satarkhan Ave.

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 8852 2083

Fax**Email**

farahmandrad.r@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

Contact

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farahmandrad.r@iums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

No - There is not a plan to make this available

Title and more details about the data/document

En All individual data of the participants in this study will be shared after unidentifiable individuals.

When the data will become available and for how long

The access period will start from 2020 to 2022

To whom data/document is available

Data will be available to researchers working in the university.

Under which criteria data/document could be used

Just for performing research

From where data/document is obtainable

Refer to the responsible person for accessing the data.

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

The data will be available one month after the responsible person's approval.

Comments