

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of metoclopramide on the mucosal nausea reflex caused by molding

Protocol summary

Study aim

Determine patients with severe nausea during molding.

Design

A Clinical trial (Before and after study), one group, blind, randomized.

Settings and conduct

the clinical trial (before and after comparison) was performed on patients referring to the Faculty of Dentistry. Patients should be well-documented in medicine, without any history of medicine allergic, there is no contraindication or precaution regarding the use of metoclopramide (such as a history of seizure, gastrointestinal bleeding) and a drug that interferes with metoclopramide (Such as phenothiazine, antidepressants, aspirin, acetaminophen). Also, there should be no stress or bad history of receiving dental care. When molding their nausea, based on a benchmark was over 5, and agreed to do this research. Patients were asked not to eat until 3 hours before molding, then their nausea was recorded in Form 1. Metoclopramide drops of Hakim plant 1 milliliter (25 drops) containing 4 milligrams of metoclopramide, hydrochloride and 1 mg of sodium saccharin (as a sweetener) was prescribed. After half an hour, the intensity of the nausea reflex was measured again by the same system

Participants/Inclusion and exclusion criteria

Patients referring to the dentistry department of the Faculty of Dentistry

Intervention groups

Metoclopramide drops of Hakim plant 1 milliliter (25 drops) containing 4 milligrams of metoclopramide, hydrochloride and 1 milligram of sodium saccharin (as a sweetener) was prescribed

Main outcome variables

Prevention of nausea reflexes during molding, which leads to a limitation of the patient's ability to accept dental procedures.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190223042808N1**

Registration date: **2019-06-03, 1398/03/13**

Registration timing: **retrospective**

Last update: **2019-06-03, 1398/03/13**

Update count: **0**

Registration date

2019-06-03, 1398/03/13

Registrant information

Name

Pantea Riahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3440 4721

Email address

panteariahi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-03, 1397/12/12

Expected recruitment end date

2019-05-12, 1398/02/22

Actual recruitment start date

2019-03-03, 1397/12/12

Actual recruitment end date

2019-05-12, 1398/02/22

Trial completion date

2019-05-12, 1398/02/22

Scientific title

Evaluation of the effect of metoclopramide on the mucosal nausea reflex caused by molding

Public title

Evaluation of the effect of metoclopramide on the mucosal nausea reflex caused by molding

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients should be healthy in health, without any history of drug or allergic allergies None of the contraindications and precautions for metoclopramide use (such as history of seizure, history of gastrointestinal bleeding, etc.) Do not take a drug that interferes with metoclopramide (eg, phenothiazine, antidepressants, aspirin, acetaminophen, etc.) These patients lacked stress and had a poor history of receiving dental care

Exclusion criteria:

Age

From **25 years** old to **56 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **28**

Actual sample size reached: **28**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee, Faculty of Dentistry - Islamic Azad University of Medical Sciences, Tehran, Iran

Street address

No. 9 neyestan 9 Ave., Pasdaran Blvd., Tehran Town

City

Tehran

Province

Tehran

Postal code

1946853314

Approval date

2019-02-25, 1397/12/06

Ethics committee reference number

1397.045

Health conditions studied

1

Description of health condition studied

Nausea reflux

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Nausea during molding

Timepoint

Periods of measurement of nausea reflux in the beginning of the study (before the intervention) and half an hour after the use of metoclopramide drop

Method of measurement

Using the 20-point ruler, the Visual Analogue Scale is set

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: One group was considered to have reported nausea reflexes before and after using metoclopramide drop.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University, Tehran Dental Branch

Full name of responsible person

Pantea Riahi

Street address

No. 9, Neyestan 9 Ave, Pasdaran Ave, Tehran Town

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Arash Azizi

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

No

Title of funding source

Islamic Azad University, Tehran Dental Branch

Proportion provided by this source

100

Public or private sector

Private

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**

Islamic Azad University

Full name of responsible person

Pantea Riahi

Position

student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

Evaluation of the effect of metoclopramide on the mucosal nausea reflex Caused by molding

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Researchers working in academia and academia will be available

Under which criteria data/document could be used

Can be used to develop dental research

From where data/document is obtainable

panteariahi@gmail.com

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

The applicant can go to the university library because the research rights belong to the Free University

Comments