Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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,1milligram 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)
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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, phenotyazine, 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
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No. 9, Neyestan Ave., Pasdaran Ave., Tehran
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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
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Person responsible for updating data

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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
pantearіahi@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