

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

The effect of matricaria chamomile essential oil inhalation on nausea of patients after Esophagogastroduodenoscopy in mashhad

Protocol summary

Study aim

The purpose of this study was to investigate the effect of inhalation of chamomile essential oil on nausea in endoscopic candidates patients.

Design

This study is a clinical trial with two group. The population will be grouped by random assignment. Sample size for each group is 80 (160 persons in total), and the sampling is continued until the target population is reached.

Settings and conduct

The aim of this study was to investigate the effect of chamomile essential oil on the anxiety of endoscopic candidate patients in the endoscopic ward of Sabzevar Vasei Hospital. The study is done double-blind. Blindness is that the subjects patients are unaware of being in the intervention or control group. Data is also encoded, and are given to the statistician without any specific intervention or control group.

Participants/Inclusion and exclusion criteria

inclusion: willing to participate in the study; Having a physician's order for doing of endoscopy ; healthy sense of smell and taste; aged between 18-70 years; able to understand and speak persian exclusion: History of taking anti-nausea drugs or with anti-nausea effects; addiction; Having nausea before endoscopy; pregnancy; Having a biopsy when needed during endoscopy; Use of sedative before endoscopy

Intervention groups

This study is done in two groups. In the intervention group, chamomile essential oil was inhaled and in the control group inhaled placebo, which in this study is sesame oil. Then, the effect of inhalation of these two substances on nausea in the two groups will be compared.

Main outcome variables

Nausea : after of endoscopy :Visual analogue scale(VAS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170515033977N2**

Registration date: **2018-09-06, 1397/06/15**

Registration timing: **registered_while_recruiting**

Last update: **2018-09-06, 1397/06/15**

Update count: **0**

Registration date

2018-09-06, 1397/06/15

Registrant information

Name

Akram Gholami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5254 7291

Email address

akram.gh1369@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-05, 1397/06/14

Expected recruitment end date

2018-11-05, 1397/08/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of matricaria chamomile essential oil inhalation on nausea of patients after Esophagogastroduodenoscopy in mashhad

Public title

The effect of matricaria chamomile essential oil on nausea of Esophagogastroduodenoscopy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

willing to participate in the study Having a doctor's order for upper gastrointestinal endoscopy healthy sense of smell and taste aged between 18-70 years able to understand and speak persian

Exclusion criteria:

History of taking anti-nausea drugs or with anti-nausea effects(for example eskazina ,...) or nauseous drugs like Opiates, Ferrous sulfate,... addiction Having nausea before endoscopy Being pregnant Having a biopsy when needed during endoscopy Use of sedative before endoscopy

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

The population of the study is randomly selected, so that the day of the sampling from the two groups of intervention and control will be determined by the lottery, and persons will not know which group they are in.

Blinding (investigator's opinion)

Double blinded

Blinding description

Sampling is easy and persons are unaware of being in the intervention or control group. After completion of the data sampling, the data will be collected and coded (code 1 and code 2) and then will be available to the statistician. Since the essential oil of Chamomile has a fragrance and a placebo without a fragrance, the sampler is aware of the groups. Therefore, can be said the double-blind trial.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Sabzevar University of Medical Sciences

Street address

the Central University of Medical Sciences- Street Asadabadi- Sabzevar

City

sabzevar

Province

Razavi Khorasan

Postal code

9613873119

Approval date

2018-08-24, 1397/06/02

Ethics committee reference number

IR.MEDSAB.REC.1397.027

Health conditions studied

1

Description of health condition studied

Endoscopic Nausea

ICD-10 code

T88.9

ICD-10 code description

Complication of surgical and medical care, unspecified

Primary outcomes

1

Description

Nausea score based on VAS scale

Timepoint

30 minutes later intervention and endoscopy

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, inhalation of 7 drops of essential oil of 10% chamomile produced by giah esans Gorgan Company. The essential oil is dipped on a sterilized gas and attached to the patient's collar of cloth.

Category

Other

2

Description

Control group: In this group, 7 drops of sesame oil produced by giah esans Gorgan Company will be given as a placebo by inhalation. In this way, the desired amount is poured on a sterilized gas with a dropper and attached to the cloth of the research unit, and 20 minutes inhalation will be performed, and then Patient endoscopy is done.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Vasei Hospital in Sabzevar

Full name of responsible person

Hasan Khalili

Street address

Tawhid shahr, Sabzevar Medical Science Campus

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Fereshte Ghorat

Street address

Research and Technology department, Sabzevar
Medical Science Campus, Tawhid shahr

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Drghorat@gmail.com

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sabzevar 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

Torbate-Jam University of Medical Sciences

Full name of responsible person

Akram Gholami

Position

Nursing Education teacher

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Sabzevar University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

Master

Other areas of specialty/work

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

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Position

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Latest degree

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Other areas of specialty/work

Nursery

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Province**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

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

Not applicable

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