

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy of smelling peppermint essential oil on patients with nausea referred to emergency department of Sina Hospital

Protocol summary

Study aim

Efficacy of Aromatherapy with peppermint essential oil on patients with nausea

Design

Randomized ,blinded , Clinical trial with control group , with parallel groups ,with 156 patients with nausea, single blind.

Settings and conduct

Patients with nausea referred to emergency department of Sina hospital; none of the staff and patients were aware of which patients received medication or placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years, Ability to understand and sign a consent form, self-reported nausea severity of 3 or greater on a verbal numeric response scale (range 0 to 10) Exclusion criteria: known allergy to peppermint essential oil, inability to inhale through the nares (include rhinitis), recent intake of antiemetic medications including Ondansetron, Metoclopramide, Granisetron, Domperidone, clinical suspicion for serotonin syndrome, pregnancy, changing the state of consciousness (to prevent the misunderstanding and signing of the informed consent form)

Intervention groups

Intervention group: The first treatment group consists of 56 patients receiving inhaled peppermint essential oil 3 times and oral placebo (which apart from the active ingredient,were similar to ondansetron tablets) for 2 minutes. Intervention group: The second treatment group consists of 56 patients receiving 4 mg oral ondansetron and inhaled peppermint essential oil 3 times for 2 minutes. Control group:Control group consists of 56 patients receiving 4 mg oral ondansetron and inhaled saline solution placebo (which apart from the active ingredient,were similar to peppermint essential oil) 3 times for 2 minutes.

Main outcome variables

nausea score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170609034406N6**

Registration date: **2020-09-23, 1399/07/02**

Registration timing: **retrospective**

Last update: **2020-09-23, 1399/07/02**

Update count: **0**

Registration date

2020-09-23, 1399/07/02

Registrant information

Name

Afshin Gharekhani

Name of organization / entity

Faculty of Pharmacy/Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-30, 1398/08/08

Expected recruitment end date

2020-09-10, 1399/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of smelling peppermint essential oil on patients with nausea referred to emergency department of Sina Hospital

Public title

Efficacy of smelling peppermint essential oil on patients with nausea referred to emergency department of Sina Hospital

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years Ability to understand and sign a consent form self-reported nausea severity of 3 or greater on a verbal numeric response scale (range 0 to 10)

Exclusion criteria:

known allergy to peppermint essential oil inability to inhale through the nares (include rhinitis) recent intake of antiemetic medications including Ondansetron, Metoclopramide, Granisetron, Domperidone clinical suspicion for serotonin syndrome pregnancy Changing the state of consciousness so as to prevent the understanding and signing of the informed consent form

Age

From 18 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: 168

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, Permuted Block Randomization method was used for entering patients in control and treatment groups. Random method and description of each method: simple randomization, block Arrange the accident stages: 1) Determine the volume of each block (blocks of 6) 2) Prepare a list of 90 blocks and assign numbers to them AABBC(1) ABCBAC(2) ABCCBA(3) ... CBAABC(90) 3) Choosing 28 random numbers between 1 and 90 4) Identification of the Treatment Assignment

Blinding (investigator's opinion)

Single blinded

Blinding description

This study was conducted in a single blind clinical trial. None of the people distributing drugs and patients were aware of which patients received the drug or placebo of Ondansetron, and were only diagnosed with the numbers given by the system to the patients.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

No 2 Central Building , Tabriz University of Medical Sciences , Golgasht Street , Tabriz

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Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2019-08-21, 1398/05/30

Ethics committee reference number

IR.TBZMED.REC.1398.581

Health conditions studied

1

Description of health condition studied

nausea

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

2

Description of health condition studied

vomiting

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

3

Description of health condition studied

pain

ICD-10 code

R52

ICD-10 code description

Pain, unspecified

4

Description of health condition studied

Duration of being in the emergency department

ICD-10 code

ICD-10 code description

5

Description of health condition studied

Patient satisfaction at discharge from emergency ward

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

nausea score

Timepoint

Immediately before intervention. 5,10,20,30,60 minutes after the intervention.

Method of measurement

Verbal Numeric Scale

2

Description

Vomiting frequency

Timepoint

Immediately before intervention. 5,10,20,30,60 minutes after the intervention.

Method of measurement

Standard questionnaire

3

Description

pain score

Timepoint

Immediately before intervention. 5,10,20,30,60 minutes after the intervention.

Method of measurement

Verbal Numeric Scale

Secondary outcomes

1

Description

Duration of being in the emergency department

Timepoint

after the intervention

Method of measurement

previously designed checklist for recording the time

2

Description

Patient satisfaction at discharge from emergency ward

Timepoint

after the intervention

Method of measurement

previously designed checklist for recording patient satisfaction

Intervention groups

1

Description

Intervention group: The first treatment group consists of 56 patients receiving inhaled peppermint essential oil 3 times and oral placebo (which apart from the active ingredient, were similar to ondansetron tablets) for 2 minutes.

Category

Treatment - Drugs

2

Description

Intervention group: The second treatment group consists of 56 patients receiving 4 mg oral ondansetron and inhaled peppermint essential oil 3 times for 2 minutes.

Category

Treatment - Drugs

3

Description

Control group: Control group consists of 56 patients receiving 4 mg oral ondansetron and inhaled saline solution placebo (which apart from the active ingredient, were similar to peppermint essential oil) 3 times for 2 minutes.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Afshin Gharekhani

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Sina Medical Research and Training Hospital Shahid Montazeri and Hafez Squares Azadi Street Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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

Yes

Title of funding source

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Afshin Gharekhani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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

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Pharmacy Student

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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

There is no further 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

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