Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jul 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 antivomiting 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 antivomiting 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 AABBCC(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

City
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
Dr Mohammad Samiei

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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
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Afshin Gharekhani
Position
Assistant professor
Latest degree
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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
Threre 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