Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

the effects of lavender aroma on intramuscular injection pain of magnesium sulfate in women with pre-eclampsia

Protocol summary

Summary

The title of this research study is the effects of lavender aroma on intramuscular injection pain of magnesium sulfate in women with pre-eclampsia. The objective of the study is comparison of pain severity of injection between lavender oil and control groups.Sweet almond oil will be used in control group. The inclusion criteria of the study are need to magnesium sulfate injection, lack of respiratory disease and sensitivity to a material. If a participant cannot tolerate inhalation of lavender oil or control substance, she will be excluded from the study.Initially the researcher will make sure the need for injection of magnesium sulfate by checking the patient's medical record. Participants will be selected considering the inclusion criteria of the study. The objectives of the study will be described to the patients and informed consent will be taken, then the participants will be assigned to lavender or control group using simple randomization method . Ten minutes before the injection of magnesium sulphate3 drops of 10% lavender oil will be added to several layers of tissue and the participant will put it 20 centimetre apart from her nose and breath naturally. For injection procedure the participant will be placed in the lateral position and 10 milliliter of 50% magnesium sulfate will be injected with the 90 degrees angle. Injection speed will be 1 milliliter per 10 seconds. Besides, other injection cares such as skin disinfection with an alcohol swap and patient privacy will be respected.The control group will be manage as the same manner described above with placebo material. Pain scores will be determined using a visual analog scale immediatly and 15 minutes after the injection.Due to special odor of essential oils, blinding of the study for the data collector and the participants is not possible. In addition, data analysis will be performed by the researcher. Finally, the data analyzed with proper statistical tests.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015031710327N12**
Registration date: **2015-07-07, 1394/04/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-07-07, 1394/04/16

Registrant information

Name
Farideh Vaziri
Name of organization / entity
Shiraz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 71 1627 9131
Email address
vazirif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2015-05-05, 1394/02/15

Expected recruitment end date

2015-10-22, 1394/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
the effects of lavender aroma on intramuscular injection pain of magnesium sulfate in women with pre-eclampsia

Public title
the effects of lavender aroma on intramuscular injection pain of magnesium sulfate in women with pre-eclampsia

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:Willingness to participate in the study; the need to an intramuscular injection of magnesium sulphate according to the commandment of the physician; lack of any medical condition such as heart and respiratory disease or psychological disorder; lack of of sensitivity to a substance or drug; lack of any lesion in injection site (buttock) exclusion criteria: Intolerance of inhalation of lavender oil or control substance during the study

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Simple randomization will be performed via closed pockets.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Science Ethics Committee of Shiraz University of Medical Sciences

Street address
Zand street

City
Shiraz

Postal code

Approval date
2015-04-19, 1394/01/30

Ethics committee reference number
IR.SUMS.REC.1394.7

Health conditions studied

1

Description of health condition studied
Pain of intramuscular injection of magnesium sulfate

ICD-10 code
Y83-Y84

ICD-10 code description
Surgical and other medical procedures as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

Primary outcomes

1

Description
Pain intensity

Timepoint
Before and After injection of magnesium sulfate

Method of measurement
Visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 10 minutes before injection, the intervention group will inhale lavender oil (10%). Lavender oil will be provide in department of pharmacology in medical school .

Category
Prevention

2

Description
Control group: 10 minutes before injection, the control group will inhale sweet almond oil.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Hafez hospital and Zeinabieh hospital

Full name of responsible person
Farideh Vaziri

Street address

School of Nursing and Midwifery, Zand street

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chanceller for Reaserch of Shiraz Univercity of Medical Sciences

Full name of responsible person

Seied Basir Hashemi

Street address

Shiraz Univercity of Medical Sciences, Zand street

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chanceller for Reaserch of Shiraz Univercity of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Farideh Vaziri

Position

Master degree

Other areas of specialty/work

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Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Farideh Vaziri

Position

Other areas of specialty/work

Street address

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Postal code

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Fax

Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty