Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison the Effect of Lavender and Geranium (Pelargonium Graveolens) on Pain after Hernia Repair Surgery of Hospitalized Children under 1 Year: a Randomized Clinical Trial

Protocol summary

Study aim
Comparison the effect of lavender and geranium essential oil on pain after hernia surgery in children under one year of age

Design
Clinical trial with control group, with parallel groups, double-blind, randomized

Settings and conduct
The study was a randomized clinical trial with participation of 60 children (three groups of 20). When the children recurrenced the ward from the operating room , children selected conveniently from the list of unilateral hernia surgery ward in Urmia Children's Hospital. Assignment to groups was based on the simple random method. Their group was first determined by the closed envelope method and their pain was immediately measured by the researcher herself with the FLACC pain instrument. After the analgesic acetaminophen injection(apotel as ward routine), the patient's pain was measured and recorded again. Then, essential oils were inhaled five times between 1, 3, 6, 9, and 12 hours after surgery and pain measured after inhalation.The essential oils were kept in front of the baby's nose for 10 minutes to be inhaled.

Participants/Inclusion and exclusion criteria
-Children under one year admitted to the pediatric surgery ward and candidates of hernia repair

Intervention groups
Two intervention groups of lavender and geranium Rose , and one group of sweet almond placebo

Main outcome variables
pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20111207008315N30**
Registration date: **2020-07-13, 1399/04/23**
Registration timing: **retrospective**

Last update: **2020-07-13, 1399/04/23**
Update count: **0**

Registration date
2020-07-13, 1399/04/23

Registrant information

Name
Leila Valizadeh

Name of organization / entity
Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 41 1479 6770

Email address
valizadehl@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-22, 1398/04/01

Expected recruitment end date
2020-07-05, 1399/04/15

Actual recruitment start date
2019-07-23, 1398/05/01

Actual recruitment end date
2019-09-21, 1398/06/30

Trial completion date
2020-09-20, 1399/06/30

Scientific title
Comparison the Effect of Lavender and Geranium

(Pelargonium Graveolens) on Pain after Hernia Repair Surgery of Hospitalized Children under 1 Year: a Randomized Clinical Trial

Public title
The effect of aromatherapy on hernia operation pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children hospitalized in the pediatric surgery department. Candidates for surgery are both male and female Family satisfaction with their children's participation in the study No respiratory problems such as asthma and allergic rhinitis Having a companion in the children participating in the study Children under one year old
Exclusion criteria:
Lack of cooperation between the patient and the patient's family during the intervention The patient's death Patient discharge before the intervention Homeless and unaccompanied child Sensitivity to the smell of lavender, geranium and sweet almond The use of perfume and other fragrances by the child or with the child Multiple surgeries Children under 2 months
Age
From **2 months** old to **1 year** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **7**
pain rating: at recurrence of operating room,after injection of apotel, after aromatherapy at1, 3 ,6,9,12 hours after surgery
Actual sample size reached: **60**
More than 1 sample in each individual
Actual sample size in each individual: **7**
Pain rating: at recurrence of operating room, after injection of apotel, after aromatherapy at 1, 3 ,6,9,12 hours after surgery
Randomization (investigator's opinion)
Randomized
Randomization description
Subjects were recruited using the convenient method and then for randomization, sealed envelopes containing one of the letters A, B, C (a total of 60: 20 of each letter) were used, which were selected by the companion and according to the contents of the envelope indicated which group it belonged to.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants and experiment doer ,evaluators were unaware of the contents of the essential oils
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz University of Medical Sciences ethic committee
Street address
Ethic committee, Research deputy building,Tabriz University of Medical Sciences, Golgasht Street, Azadi Street,Tabriz, East Azerbaijan, Iran.,
City
Tabriz
Province
East Azarbaijan
Postal code
00984134796770
Approval date
2018-09-10, 1397/06/19
Ethics committee reference number
IR.TBZMED.REC.1397.489

Health conditions studied

1

Description of health condition studied
Comparison the effect of lavender and geranium essential oil
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain score
Timepoint
0, half hour after surgery without aromatherapy, and in 1,3,6,9,12 hours after surgery with aromatherapy
Method of measurement
FLACC pain rating scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group; Lavender: When children enter the ward from the operating room, first their group is determined by the closed envelope method and immediately their pain is measured with FLACC pain tool by the researcher herself and then according to the ward routine section of acetaminophen as a painkiller. Once again after the analgesic (Acetaminophen/Apotel) injection as ward routine, the patient's pain is measured and recorded. Then, at intervals of 1, 3, 6, 9 and 12 hours after the operation, lavender essential oil is inhaled five times and the pain is measured thirty minutes since inhalation starts or 20 minutes after ending the each aromatherapy. The packages (5 dark glasses) are prepared and coded under the supervision of a pharmacologist and by another person, and the researcher conducting the intervention does not know the nature of the essential oil in the containers. The container be placed in front of the patient's nose for 10 minutes at a distance of 10 cm. The data is analyzed in SPSS software.

Category

Treatment - Drugs

2

Description

Intervention group, geranium rose: When children enter the ward from the operating room, first their group is determined by the closed envelope method and immediately their pain is measured with FLACC pain tool by the researcher herself and then according to the ward routine section of acetaminophen as a painkiller. Once again after the analgesic (Acetaminophen/Apotel) injection as ward routine, the patient's pain is measured and recorded. Then, at intervals of 1, 3, 6, 9 and 12 hours after the operation, Geranium Rose essential oil is inhaled five times and the pain is measured thirty minutes since inhalation starts or 20 minutes after ending the each aromatherapy. The packages (5 dark glasses) are prepared and coded under the supervision of a pharmacologist and by another person, and the researcher conducting the intervention does not know the nature of the essential oil in the containers. The container be placed in front of the patient's nose for 10 minutes at a distance of 10 cm. The data is analyzed in SPSS software.

Category

Treatment - Drugs

3

Description

Control group, sweet almond placebo: When children enter the ward from the operating room, first their group is determined by the closed envelope method and immediately their pain is measured with FLACC pain tool by the researcher herself and then according to the ward routine section of acetaminophen as a painkiller. Once again after the analgesic (Acetaminophen/Apotel) injection as ward routine, the patient's pain is measured and recorded. Then, at intervals of 1, 3, 6, 9 and 12 hours after the operation, sweet almond oil is inhaled five times and the pain is measured thirty minutes since inhalation starts or 20 minutes after ending the each aromatherapy. The packages (5 dark glasses) are prepared and coded under the supervision of a pharmacologist and by another person, and the researcher conducting the intervention does not know the nature of the essential oil in the containers. The container be placed in front of the patient's nose for 10 minutes at a distance of 10 cm. The data is analyzed in SPSS software.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Motahari hospital

Full name of responsible person
Razieh Alipour

Street address
Ayatollah Kashani street, Urmia.

City
Urmia

Province
West Azarbaijan

Postal code
57147

Phone
+98 44 3223 7077

Fax
+98 44 3223 7077

Email
raziehalipour23@gmail.com

Web page address
https://motahari.umsu.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Mohammad Samiei

Street address
Azadi Stree, Street Golgasht

City
Tabriz

Province
East Azarbaijan

Postal code
5165665811

Phone
+98 41 3335 7310

Fax
+98 41 3335 7310

Email
Samiei.moh@gmail.com
Web page address
https://researchvice.tbzmed.ac.ir
Grant name
-
Grant code / Reference number
TBZMED.REC.13947.489
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
Leila Valizadeh
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Shariati St. School of Nursing and Midwifery
City
Tabriz
Province
East Azarbaijan
Postal code
51389477977
Phone
+98 41 3479 6770
Fax
+98 41 3479 6770
Email
valizadehl@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Leila Valizadeh
Position
Faculty member
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
School of Nursing and Midwifery, Shariati street.
City
Tabriz
Province
East Azarbaijan
Postal code
5138947977
Phone
+98 41 3479 6770
Fax
+98 41 3479 6770
Email
valizadehl@tbzmed.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Leila Valizadeh
Position
Faculty member
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
School of Nursing and Midwifery, Shariati street.
City
Tabriz
Province
East Azarbaijan
Postal code
5138947977
Phone
+98 41 3479 6770
Fax
+98 41 3479 6770
Email
valizadehl@tbzmed.ac.ir

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
-
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

No - There is not a plan to make this available