

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 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 recurred 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)

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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 at 1, 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

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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

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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

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

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Other areas of specialty/work

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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

-

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