Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of aromatherapy with Rosa damascene mill and pelargonium graveolens on post operative pain intensity in hospitalized children

Protocol summary

Summary

The aim of this study was to evaluate the effectiveness of aromatherapy on the postoperative pain in children in a double blind placebo-controlled clinical trial we selected 96 children between hospitalized children in surgical unit, with 3-6 years old in ease way and divided randomly into three groups. Patient in group A were given inhalation aromatherapy with Rosa damascene mill and in group B, pelargonium graveolens and group C were given almond oil as a placebo, although children in each groups and researcher and analyzer were unknowable of kind of aroma. Inhalation aromatherapy used at the first time of child enter to ward as the 0 time and then at 3, 6, 9 and 12 hours afterward and common treatment to palliative pain were used in each three groups. 30 minutes after per time aromatherapy, the postoperative pain in children were evaluated with the Toddler Preschooler Postoperative Pain Scale. Data was statistically analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014030516850N1**
Registration date: **2014-05-06, 1393/02/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-05-06, 1393/02/16

Registrant information

Name

Motahare Sirousfard

Name of organization / entity

Isfahan University of Medical Scencie, Nursing and Midvifry Faculty

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2013-06-22, 1392/04/01

Expected recruitment end date

2013-09-06, 1392/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aromatherapy with Rosa damascene mill and pelargonium graveolens on post operative pain intensity in hospitalized children

Public title

Effect of Aromatherapy in post operative pain in children

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age between 3-6 years old; hospitalized for surgery; both male and female; having many surgery slice; hospitalized in PI CU; not having any parents; having respiratory disease; used of narcotic or opiate in last week; having history of rhinitis or dermatitis in children or their parent; having chronic pain; used of complimentary medicine in last week. Exclusion criteria: having no tendency to continues

treatment; discharge or child died;having symptom of rhinitis or dermatitis; having infection symptom in surgical lesion; having symptom of illness in duration of study.

Age
From **3 years** old to **6 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
3 groups (2 of interval groups and 1 control group) and 5 Times

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
IsfahanUniversity of Medical Scencie

Street address
Isfahan University Medical Scencie, Hezar jreeb street

City
Isfahan

Postal code

Approval date
2013-06-20, 1392/03/30

Ethics committee reference number
1033

Health conditions studied

1

Description of health condition studied
Pain

ICD-10 code
R52.0

ICD-10 code description
Acute pain

Primary outcomes

1

Description
postoperative pain in children

Timepoint
0, 3, 6, 9 & 12 hourse after entire from operative room to ward

Method of measurement
Toddler Preschooler Postoperative Pain Scale

Secondary outcomes

empty

Intervention groups

1

Description
aromatherapy- Rosa damascena mill (intervention group 1) 1-2 drop in cotton pad, in 30 cm interval of child head

Category
Treatment - Other

2

Description
aromatherapy- pelargonium graveolens (intervention group 2) 1-2 drop in cotton pad, in 30 cm interval of child head

Category
Treatment - Other

3

Description
aromatherapy- almond oill (placebo)-(control group) 1-2 drop in cotton pad, in 30 cm interval of child head

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Hosein Hospital

Full name of responsible person
F. Samouie (RN)

Street address
Emam Khomeini street

City
Isfahan

2

Recruitment center

Name of recruitment center
alzahra Hospital

Full name of responsible person
mansouri (RN)
Street address
shohadaye Soffe
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Scencie
Full name of responsible person
Dr. Peyman Adibi
Street address
Isfahan University of Medical Scencie ,Hezarjreeb street
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Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan University of Medical Scencie
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

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Person responsible for updating data

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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