

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

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Isfahan University of Medical Scencie ,Hezarjreeb street

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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

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****Contact****Name of organization / entity**

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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