

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 1522 9759

##### Email address

msf222mmh@yahoo.com

##### 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

**City**

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

Isfahan University of Medical Scencie, Nursing and Midvifry Faculty

**Full name of responsible person**

Motahareh Sirousfard

**Position**

Master of Pediatric Nursing

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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*