

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 2026

### The effect of aromatherapy with “Rosa Damascena” on sleep quality of children with sleep disorder

#### Protocol summary

##### Summary

The goal of this study is determining aromatherapy with Rosa damascene on sleep quality of children with sleep disorder. Inclusion criteria: age at diagnosis of 12-5 years with complaint's of sleep disorder; No having allergy, asthma, atopic dermatitis, Nasal health; Not taking any medication or sleep inducing action; No other underlying disease drug consumption with effect on sleep Exclusion criteria: Outside the range specified age; Having allergic diseases; Nasal disorders; Using that affects on sleep. The sample size is 30. After entering children and recording data and filling BEARS questionnaire, they use aromatherapy before sleeping in 20 minutes and after 2 weeks will reevaluate. Evaluation based on changes in sleep onset problems, excessive daytime sleepiness, waking up during the night, order and long sleep and snoring done.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015062222865N1**

Registration date: **2015-07-12, 1394/04/21**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2015-07-12, 1394/04/21

##### Registrant information

##### Name

Armaghan Sadat Keyhanmehr

##### Name of organization / entity

Department of Traditional Medicine, School of Traditional Medicine, Shahid Beheshti University of Me

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8877 3521

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Shahid Beheshti University of Medical Sciences, school of traditional medicine

##### Expected recruitment start date

2015-07-23, 1394/05/01

##### Expected recruitment end date

2016-07-22, 1395/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of aromatherapy with “Rosa Damascena” on sleep quality of children with sleep disorder

##### Public title

The effect of aromatherapy with Rosa Damascena on sleep quality of children

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: age at diagnosis of 12-5 years with complaint's of sleep disorder; No having allergy, asthma, atopic dermatitis, Nasal health; Not taking any medication or sleep inducing action; No other underlying disease drug consumption with effect on sleep Exclusion criteria: Outside the range specified age; Having allergic diseases; Nasal disorders; Using that affects on sleep

##### Age

From **5 years** old to **12 years** old  
**Gender**  
Both  
**Phase**  
3  
**Groups that have been masked**  
*No information*  
**Sample size**  
Target sample size: **30**  
**Randomization (investigator's opinion)**  
N/A  
**Randomization description**  
**Blinding (investigator's opinion)**  
Not blinded  
**Blinding description**  
**Placebo**  
Not used  
**Assignment**  
Single  
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Shahid Beheshti university of medical science

##### Street address

Chamran high way-Velenjak ave

##### City

Tehran

##### Postal code

#### Approval date

2015-06-14, 1394/03/24

#### Ethics committee reference number

171

## Health conditions studied

### 1

#### Description of health condition studied

Sleep disorders

#### ICD-10 code

G47

#### ICD-10 code description

Sleep disorders

## Primary outcomes

### 1

#### Description

onset sleep disorders

#### Timepoint

before intervention-after two weeks

## Method of measurement

questionnaire

### 2

#### Description

Excessive daytime sleepiness

#### Timepoint

before intervention-after two weeks

#### Method of measurement

questionnaire

### 3

#### Description

Waking up during the night

#### Timepoint

before intervention-after two weeks

#### Method of measurement

questionnaire

### 4

#### Description

Length of time in order to sleep

#### Timepoint

before intervention-after two weeks

#### Method of measurement

questionnaire

### 5

#### Description

snoring

#### Timepoint

before intervention-after two weeks

#### Method of measurement

questionnaire

## Secondary outcomes

### 1

#### Description

sneezing

#### Timepoint

before and after intervention

#### Method of measurement

questionnaire

### 2

#### Description

cough

#### Timepoint

before and after intervention

#### Method of measurement

questionnaire

### 3

#### Description

other symptoms

**Timepoint**

before and after intervention

**Method of measurement**

questionnaire

**Intervention groups****1****Description**

drop of Rosa damascene, 10%,5 drops, nights in 20 minutes before bedtime for two weeks.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Department of Traditional Medicine, School of Traditional Medicine, Shahid Beheshti University of Me

**Full name of responsible person**

Armaghan Keyhanmehr

**Street address**

8, Shams Alley, Across from Shaid Abbaspour St, Vali Asr Ave.,

**City**

Tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Department of Traditional Medicine, School of Traditional Medicine, Shahid Beheshti University of Me

**Full name of responsible person**

sommaye esmaili

**Street address**

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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**

Department of Traditional Medicine, School of Traditional Medicine, Shahid Beheshti University of Me

**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**

a Department of Traditional Medicine, School of Traditional Medicine, Shahid Beheshti University of

**Full name of responsible person**

Armaghan Sadat Keyhanmehr

**Position**

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**Other areas of specialty/work****Street address**

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assistant professor

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**Other areas of specialty/work**

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a\_keyhanmehr@gmail.com

**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*