

# 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

keyhanmehr@sbmu.ac.ir

##### 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**

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

**City**

Tehran

**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**

student of traditional medicinephd

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

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

**City**

Tehran

**Postal code****Phone**

+98 21 8877 3521

**Fax****Email**

a\_keyhanmehr@yahoo.comar.keyhanmehr@gmail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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

**Full name of responsible person**

Mina Movahhed

**Position**

assistant professor

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

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

**City**

Tehran

**Postal code****Phone**

+98 21 8877 3521

**Fax****Email**

m\_movahhed@sbmu.ac.ir

**Web page address****Person responsible for updating data****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**

student of traditional medicine-phd

**Other areas of specialty/work**

**Street address**

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

**City**

Tehran

**Postal code**

**Phone**

+98 21 8877 3521

**Fax**

**Email**

a\_keyhanmehr@yahoo.com  
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*