

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of aromatherapy with orange essential oils on sleep quality in the hospitalized school-age children whit ALL

Protocol summary

Summary

The present research aims at examining the effect of inhaling essential oil of orange on the quality of sleep among children with acute lymphoblastic leukemia. The research is a semi-experimental study in which 60 children admitted to the oncology unit in Shafa Hospital affiliated to Jondi-Shapoor Medical Sciences University, Ahvaz, Iran, were studied during 2014 using two test and control groups. The research instruments were demographic information questionnaire and the standard CSHQ questionnaire. The research sample included hospitalized school-aged children with acute lymphoblastic leukemia and with sleep quality score of higher than 41. Intervention in the test group included inhaling essential oil of orange for three days in week and three times each day; similar intervention was used in the control group except that distilled water as placebo instead of essential oil of orange was applied.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014090919102N1**

Registration date: **2015-02-04, 1393/11/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-02-04, 1393/11/15

Registrant information

Name

Masoomeh Noruzi Zamenjani

Name of organization / entity

Ahvaz Jundishapour University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+686 113738331

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapour University of Medical Sciences

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2014-11-22, 1393/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aromatherapy with orange essential oils on sleep quality in the hospitalized school-age children whit ALL

Public title

The effect of aromatherapy with orange essential oils on sleep quality in the hospitalized school-age children whit ALL

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Children that are at school age (6-12 years); Children who receive treatment procedure for ALL; the score of sleep quality more than 41; Children who have no verbal problem; no mental problems; no allergic rhinitis or respiratory problems; no history of hospitalization for psychological illness. Exclusion criteria: during the intervention receive medical treatment outside the usual treatment guidelines;

concurrent treatment with other essential oils during the intervention; allergic rhinitis or respiratory problems occurred during the intervention; a crisis or an unpredictable accident occurs.

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapour University of Medical Sciences

Street address

Ahvaz Jundishapour University of Medical Sciences,
Golestan highway, Ahvaz

City

Ahvaz

Postal code

6135715794

Approval date

2014-02-22, 1392/12/03

Ethics committee reference number

ajums.REC.1393.12

Health conditions studied

1

Description of health condition studied

acute lymphoblastic leukemia

ICD-10 code

C91.0

ICD-10 code description

Acute lymphoblastic leukaemia [ALL]

Primary outcomes

1

Description

sleep quality

Timepoint

Before and after the interventions

Method of measurement

Children Sleep Habits Questionnaire CSHQ

Secondary outcomes

empty

Intervention groups

1

Description

Intervention in the control group included inhaling distilled water as placebo for three days in a week and three times each day (10am, 4pm, 10pm). In control group we measure the score of sleep quality once before intervention and once after end of interventions.

Category

Placebo

2

Description

Intervention in the test group included inhaling essential oil of orange for three days in a week and three times each day (10am, 4pm, 10pm). In test group we measure the score of sleep quality once before intervention and once after end of interventions.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Hospital

Full name of responsible person

H. Alijani Renani

Street address

Ahvaz Jundishapour University of Medical Sciences,
Golestan highway, Ahvaz

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapour University of Medical Sciences

Full name of responsible person

Dr Koorush Zare

Street address

Ahvaz Jundishapour University of Medical Sciences,
Golestan highway, Ahvaz

City

Ahvaz

Grant name

Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Ahvaz Jundishapour University of Medical Sciences

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

Ahvaz Jundishapour University of Medical Sciences

Full name of responsible person

masoomah noruzi zamengani

Position

Graduate student

Other areas of specialty/work

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**Person responsible for scientific
inquiries**

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Position

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Other areas of specialty/work

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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