

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

The effect of lavender oil aromatherapy on infantile colic

Protocol summary

Summary

It's estimated that up to 40% of all infants have colic. An infant with colic may affect family stability and be a cause of short-term anxiety or depression in the mother. It may also contribute to exhaustion and stress in the parents. This study aimed to assess effectiveness of lavender oil aromatherapy on infantile colic. Inclusion criteria included: parent's willingness to participate their infants, physician diagnosis for infantile colic, without any medical problem, aged 4-8 weeks, and no chemical drug consumption for colic. Methods: in pediatrics clinics, infants who need to treat colic are assigned to lavender group or control group (sweet almond oil group) randomly. Mothers of the infants will be trained to use the aromatherapy oils twice a day for 6 days, three days inhalation and following three days apply to abdominal skin. Using a sterile 4 by 4 gauze pad with 3- 4 drops of oil dripped on, inhalation aromatherapy will be performed for 15- 20 minutes. The gauze pad will be put next to infant's head. Change in colic will be assessed by phone to mothers twice a day according to a self constructed check list by the researcher. If the infant cannot tolerate the aromatherapy oils, the intervention will be discontinued immediately. This study is a double blind research. The parents and also research assistant that will collect the data are blind to materials of aromatherapy. Furthermore, in this study 1% lavender oil will be used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016072410327N15**

Registration date: **2016-09-01, 1395/06/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-09-01, 1395/06/11

Registrant information

Name

Farideh Vaziri

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1627 9131

Email address

vazirif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-11-05, 1395/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of lavender oil aromatherapy on infantile colic

Public title

The effect of lavender oil aromatherapy on infantile colic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: parent's willingness to participate their infants; physician diagnosis for infantile colic; without any medical problem; aged 4-8 weeks, and no chemical drug consumption for colic. exclusion criteria: Intolerance of aromathrapy oil during the study

Age
From **1 month** old to **3 months** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Sciences

Street address
Zand street

City
Shiraz

Postal code

Approval date
2016-01-24, 1394/11/04

Ethics committee reference number
IR.SUMS.REC.1394.186

Health conditions studied

1

Description of health condition studied
Colic in infants

ICD-10 code
R10.4

ICD-10 code description
Other and unspecified abdominal pain

Primary outcomes

1

Description
Crying duration

Timepoint

before intervention and days1, 2,3,4,5, and 6 after intervention

Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

intervention group: Lavender aromatherapy twice a day for 6 days

Category

Treatment - Other

2

Description

control group: Sweet almond aromatherapy as placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Reza pediatrics clinic

Full name of responsible person
Zahra Sahebkrum

Street address
Zand street

City
Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr Basir Hashemi

Street address
Zand street

City
Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz
Postal code
Phone
+98 71136474254
Fax
Email
roose82003@yahoo.com
Web page address

Person responsible for general inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Farideh Vaziri
Position
MS
Other areas of specialty/work
Street address
Zand street
City
Shiraz
Postal code
Phone
+98 71136281497
Fax
Email
roose82003@yahoo.com, vazirif@sums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Farideh Vaziri
Position
MS
Other areas of specialty/work
Street address
Zand street
City

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Farideh Vaziri
Position
MS
Other areas of specialty/work
Street address
Zand street
City
Shiraz
Postal code
Phone
+98 71 1235 7282
Fax
Email
vazirif@sums.ac.ir
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