Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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 clinc
Full name of responsible person
Zahra Sahebkram
Street address
Zand street
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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

Person responsible for general inquiries

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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