

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Evaluation of the effectiveness of chamomile oil (*Matricariachamomilla* L.) topical application, as a supplement therapy, compared with placebo in the improvement of infantile colic symptoms (crying time): a randomized controlled clinical trial

Protocol summary

Summary

The main purpose of this study is to evaluate the effectiveness of topical application of chamomile oil (*Matricariachamomilla* L.) compared with placebo for improving the symptoms (crying time) of infantile colic. In this double blind clinical trial done in 1395, 68 infants attending to a pediatric clinic in Sabzevar were randomly allocated into the intervention (A) and control (B) groups through block randomization method. Inclusion criteria: being at the age of 2 weeks to 4 months, presence of infantile colic symptoms and no systemic disease diagnosed by specialists, parental consent. In the intervention group, Chamomile oil was applied on the baby belly by mother's palms, three times a day and any time ten drops, for 14 days. In control group, Paraffin oil as a placebo was used in the same way as intervention group to homogenize the massage in both groups. Researcher, after educating how to use the drug / placebo to the parents, followed them by phone call or appointment in the clinic during the period of treatment. The effectiveness of Chamomile oil was evaluated based on the change in the frequency and duration of crying and infants' sleep during 24 hours as the main outcome of study in the day before treatment, the first day, seventh and fourteenth day after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017032818951N2**

Registration date: **2017-04-25, 1396/02/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-04-25, 1396/02/05

Registrant information

Name

Fereshteh Ghorat

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Sabzevar University of Medical Sciences

Expected recruitment start date

2016-12-28, 1395/10/08

Expected recruitment end date

2017-03-15, 1395/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of chamomile oil (*Matricariachamomilla* L.) topical application, as a supplement therapy, compared with placebo in the improvement of infantile colic symptoms (crying time): a randomized controlled clinical trial

Public title

The effect of topical Chamomile oil in the treatment of infantile colic.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: infants with infantile colic (based on the criteria Wessel and a pediatrician); at the age of two weeks to four months; term infants (gestational age more than 37 weeks); infants with birth weight more than 2500 gr; absence of underlying diseases and congenital disorders. Exclusion criteria: failure to thrive (according to growth curves); major medical conditions (immune deficiency, growth and development retardation, genetic disorders); presence of rash in the area of topical medication therapy.

Age

From **14 days** old to **4 months** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Patients were placed in the intervention (A) and control (B) groups through block randomization method.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Sabzevar University of Medical Sciences

Street address

Medical campus, Sabzevar University of Medical Sciences, Daneshgah boulevard

City

Sabzevar

Postal code

9613873136

Approval date

2016-12-28, 1395/10/08

Ethics committee reference number

IR.MEDSAB.REC.1395.130

Health conditions studied**1****Description of health condition studied**

Infantile colic

ICD-10 code

R10.4

ICD-10 code description

Other and unspecified abdominal pain

Primary outcomes**1****Description**

Infant crying time (in minutes) in 24 hours

Timepoint

The day before the treatment, the first day, the seventh and fourteenth day after treatment

Method of measurement

Register crying time in infants in terms of minutes per day in the form of journaling, maternal infant

Secondary outcomes**1****Description**

Infant sleep duration in minutes in 24 hours

Timepoint

The day before the treatment, the first day, the seventh and fourteenth day after treatment

Method of measurement

Register infant sleep duration in minutes per day in the form of journaling, maternal infant

2**Description**

Number of infant's crying in 24 hours

Timepoint

The day before the treatment, the first day, the seventh and fourteenth day after treatment

Method of measurement

Register number of infant crying during the day and in the form of journaling, maternal infant

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

In the intervention group, ten drops of Chamomile oil was rubbed on the baby's belly by mother's palms, 15 times clockwise and 15 times counter-clockwise, three times a day, for 14 consecutive days.

Category

Treatment - Drugs

2

Description

In the control group, ten drops of Paraffin oil was rubbed on the baby's belly by mother's palms, 15 times clockwise and 15 times counter-clockwise, three times a day, for 14 consecutive days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric Clinic

Full name of responsible person

Doctor Hassan Salehipour, Neonatal fellowship

Street address

Dr Salehipour's office, next to Heshmatieh Hospital,
Bagh Melli

City

Sabzevar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Sabzevar University of
Medical Sciences

Full name of responsible person

Doctor Mohammadzade

Street address

Vice Chancellor for research, Sabzevar University of
Medical Sciences, Daneshgah boulevard

City

Sabzevar

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Behzad Afzali

Position

Medical Student

Other areas of specialty/work

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Position

Professor, Neonatal fellowship

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empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty

Sharing plan

Deidentified Individual Participant Data Set (IPD)