

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The efficacy of topical Chamomile oil (*Matricaria chamomilla*), an Iranian traditional medicine, compared with placebo, on infantile colic: Triple blind clinical trial

Protocol summary

Summary

Objective: To determine the efficacy of topical Chamomile oil, compared with placebo, on infantile colic. Inclusion criteria: Infants who had Wessel factor; Full term ; Birth Weight 2500-4000 gram; Breast Milk Feeding; Filling Consent Form; Age: 2-13 week. Exclusion criteria: Failure to thrive; Lactose intolerance and Allergic to Milk; Use Of Antibiotic; Use Of Formula; Acute or Chronic disease; Skin allergy to oils; failure in conducting the intervention correctly. Design: Randomize, Triple blind clinical study was performed on 102 breastfed infants, who were coming to Children medical center or Traditional Iranian Medicine clinic. At the first, their mothers 4 days, note the hours of the cry. If they had wessle's criteria (episodes of fussy crying lasted _3 hours a day and episodes _3 days in the 1 week) and written informed consent form, enrolled in this project. Randomize: Colicky infants were randomly assigned to receive Chamomile oil or placebo. The bottles were coded and blinded by the pharmacist for the participants and physicians and methodologist. both groups give Simethicone (5-10 drops 3/day). The mother is taught, 2drops of oil spills on the children's arm and wait 3 hours, in the absence of complication, 5-7 drops of oil spill on the abdomen, below the ribs to the lower abdomen and 5-7 drops both sides of the vertebral column , and spread to be completely impregnated with oil. This is at least 4 times as needed up to 6 times a day. parents were asked to fill in a structured diary to record the daily crying time (minute) , stool characteristics and frequency, and any adverse effect observed on each days of the study. Duration of intervention is 7 days. primary outcome is duration of infantile crying in 24 hours: 4 days a week before intervention and for 7 days in the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016111530903N1**

Registration date: **2017-03-03, 1395/12/13**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-03-03, 1395/12/13

Registrant information

Name

Fatemeh Mohamadi Sormeh

Name of organization / entity

School of Traditional Medicine, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The efficacy of topical Chamomile oil (Matricaria chamomilla), an Iranian traditional medicine, compared with placebo, on infantile colic: Triple blind clinical trial

Public title
The efficacy of Chamomile oil on infantile colic

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Infants who had Wessel factor; Full term ; Birth Weight 2500-4000 gram; Breast Milk Feeding; Filling Consent Form; Age: 2-13 week. Exclusion criteria: Failure to thrive; Lactose intolerance and Allergic to Milk; Use Of Antibiotic; Use Of Formula; Acute or Chronic disease; Skin allergy to oils; failure in conducting the intervention correctly.

Age
From **14 days** old to **3 months** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **102**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Science

Street address

Qods Street, Bolvar Keshavarz

City

Tehran

Postal code

Approval date

2017-01-24, 1395/11/05

Ethics committee reference number

IR.TUMS.VCR.REC.1395.1531

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

Duration of infantile crying in 24 hours for 7 days

Timepoint

4 days a week before intervention and 7 days in the intervention time

Method of measurement

recording of crying time by mother

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition of Simethicon 5-7 drops both sides of the vertebral column , and spread to be completely impregnated with oil. This is at least 4 times as needed up to 6 times a day is done for 7 days

Category

Treatment - Drugs

2

Description

Control group: In addition of Simethicon 5-7 drops both sides of the vertebral column , and spread to be completely impregnated with oil. This is at least 4 times as needed up to 6 times a day is done for 7 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Traditional medicine, Tehran University of Medical Science

Full name of responsible person

Fatemeh Mohamadi Sormeh

Street address

Sarparast St, Taleghani St, ValiAsr Blvd.

City

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2**Recruitment center****Name of recruitment center**

Children Medical Center Hospital

Full name of responsible person

Dr Fatemeh Mohamadi Sormeh

Street address

Garib St, Bolvar Keshavarz

City

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, school of Traditional Medicine, Tehran University of Medical Science

Full name of responsible person

Dr Roja Rahimi

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Sarparast St, Taleghani St, ValiAsr Blvd.

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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, school of Traditional Medicine, Tehran University of Medical Science

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**

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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