Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Examination of the effect of Iranian cumin extract (Bunium persicum) on infantile colic: A randomized double-blind trial

Protocol summary

Study aim

Determining and comparing the effect of Iranian cumin extract (Bunium persicum) on infant colic between control and intervention groups

Design

A randomised, double blind Clinical trial with a control group, with parallel groups, phase 3 on 80 patients. For randomization, random allocation rule was used to assign red and blue cards.

Settings and conduct

This randomized double-blind clinical trial will be conducted on children with colic referred to Imam Ali Pediatric Clinic in 1402. The study will be double-blind so that the researcher and parents will not be aware of the grouping (intervention or control).At the beginning of the study, a written consent form will be obtained from the parents after providing explanations. The intervention group will be treated with relaxation techniques and cumin extract, and the control group will be treated with relaxation techniques and placebo. A checklist regarding the child's symptoms will be provided to the parents to record the infant's symptoms during the study. At the end, the coded data will be entered into the spss 22 table and will be analyzed.

Participants/Inclusion and exclusion criteria

inclusion criteria: previously diagnosed infantile colic; No antibiotic use in the last two weeks; Absence of underlying diseases or congenital disorders exclusion criteria: No relevant diagnosis of colic and no meeting of the inclusion criteria

Intervention groups

In addition to calming techniques, the intervention group will receive 0.5 mL of Bunium persicum oral extract daily in the form of drops (obtained from Barij Essential Oil Company) for two weeks. The control group will not be deprived of the standard treatment, which is relaxation techniques, and will receive a placebo with the same color and smell as Iranian cumin extract.

Main outcome variables

duration of crying; times of crying; sleep duration; Number of bowel movements

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230714058777N1**
Registration date: **2023-09-02, 1402/06/11**
Registration timing: **prospective**

Last update: **2023-09-02, 1402/06/11**
Update count: **0**

Registration date

2023-09-02, 1402/06/11

Registrant information

Name

Amin Amini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3337 5350

Email address

st-amini.a@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-11, 1402/06/20

Expected recruitment end date

2024-01-20, 1402/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Examination of the effect of Iranian cumin extract (Bunium persicum) on infantile colic: A randomized double-blind trial

Public title
The effect of Iranian cumin extract (Bunium persicum) on infantile colic

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Infantile colic based on wessel`s criteria (paroxysms of crying episodes; lasting for more than 3h in a day; occuring three or more days per week for at least three weeks) diagnosed by pediatrician age: 3-13 weeks Gastational age: more than 37 weeks at birth weight: more than 2500 gr at birth Absence of underlying diseases or congenital disorders No antibiotic use in the last two weeks

Exclusion criteria:
failure to thrive Recent use of antibiotics age less than 3 weeks and more than 13 weeks low birth weight prematurity

Age
From **21 days** old to **91 days** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
The researcher assigns a number to each patient using the random allocation rule method and then puts the cards on which the patient's number is written in an envelope in a random order. In this method, according to the sample volume, two sets of card with different colors with the same number equal to the total volume of the sample are put inside the envelope, then the eligible people entered into the study are randomly assigned to a color coded card from the envelope. According to the researcher's definition, if the red card is taken, they will enter the intervention group, and if the blue card is taken, they will enter the control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
In our method of blinding, the patient's companion, who is usually one of the parents, is unaware of the type of drug used. Also, the person collecting the information is unaware of the type of drug received by the patient. Placebo has the same color and smell as Bunium extract. The extract will be provided by Barij Company in the same form and packaging in a coded form, under the supervision of a pharmacology expert.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahrekord University of Medical Sciences

Street address
Ayatollah Kashani St.

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
۸۸۱۵۷۱۳۴۷۱

Approval date
2023-05-31, 1402/03/10

Ethics committee reference number
IR.SKUMS.MED.REC.1402.019

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
The average duration of crying in infant

Timepoint
the beginning of the study and 7, 14, 21 and 28 days after the start of the study

Method of measurement
check list

2

Description
The number of times the infant cries

Timepoint
the beginning of the study and 7, 14, 21 and 28 days after the start of the study
Method of measurement
checklist

3

Description
duration of sleep
Timepoint
the beginning of the study and 7, 14, 21 and 28 days after the start of the study
Method of measurement
check list

4

Description
number of defications
Timepoint
the beginning of the study and 7, 14, 21 and 28 days after the start of the study
Method of measurement
chrcklist

5

Description
age
Timepoint
the beginning of the study
Method of measurement
the history

6

Description
sex
Timepoint
the beginning of the study
Method of measurement
the history

7

Description
birth weight
Timepoint
the beginning of the study
Method of measurement
the history

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:in addition to relaxation techniques, the intervention group will receive 0.5 mL of oral extract of Bunium persicum 4 times a day in the form of oral drops (provided by Barij Company) for two weeks.
Category
Treatment - Drugs

2

Description
Control group:The control group will not be deprived of the standard treatment, which is relaxation techniques. Relaxation techniques includeing making soothing sounds or singing songs, using slow and rhythmic shaking movements, walking, and using mild vibration-like movements such as the movements of cars are taught to parents at the beginning of the study.In addition, the control group will receive placebo in the form of drops with the same color and smell as cumin extract.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Ali clinic
Full name of responsible person
Hassan Talakesh
Street address
Shariati St.
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Chahar-Mahal-va-Bakhtiari
Postal code
8815713471
Phone
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Email
info@skums.ac.ir
Web page address
https://imamaliclinic.skums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Elham Reisi
Street address
Kashani st.
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Email
vcrt@skums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Shahre-kord University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Amin Amini

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
Family Physician

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Parastar st.

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Hassan Talakesh

Position
Assistant professor

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Person responsible for updating data

Contact

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Hassan Talakesh

Position
Assistant professor

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Subspecialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Checklists completed by mothers include individual data that can be published after de-identification

When the data will become available and for how long

The start of the period of access to data and documentation files will be 6 months after the results are published

To whom data/document is available

The data obtained from the study will be accessible to researchers working in academic and scientific centers as well as people working in the pharmaceutical industry.

Under which criteria data/document could be used

The data obtained from the study can be used in order to help make the right medicine to control infant colic.

From where data/document is obtainable

Contact the scientific officer of the project via email at talakesh.h@skums.ac.ir

What processes are involved for a request to access data/document

After correspondence with the scientific officer of the project through the e-mail address talakesh.h@skums.ac.ir, within two weeks after checking the purpose of data access, their request will be answered.

Comments