

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the reduction of infant colic symptoms following casein-free diet in children with and without a history of parental atopy

Protocol summary

Study aim

Comparison of the reduction of infant colic symptoms following casein-free diet in children with and without a history of parental atopy

Design

Non-randomized clinical trial, with parallel groups, without blinding, without control group, phase 3 on 206 patients.

Settings and conduct

All infants suffering from colic referred to Amirkabir Hospital in Arak will be included in the study. Parents of infants will be examined by an asthma and allergy specialist and any evidence of atopy including asthma, atopic dermatitis and allergic rhinitis will be reported by him. Patients will be divided into two groups with atopy and without atopy. Then, babies in both groups will be subjected to a casein-free diet (removing dairy products from the mother's diet) for one month. Blinding will not be done in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 15 months to 3 months, suffering from infantile colic. Exclusion criteria: lack of parental consent.

Intervention groups

In the first intervention group, 103 breastfed children who have a history of atopy in their parents and are referred for the treatment of infantile colic are subjected to a casein-free diet (removing dairy products from the mother's diet) for one month. In the second intervention group, 103 breastfed children who have no history of atopy in their parents and are referred for the treatment of infantile colic are subjected to a casein-free diet (removal of dairy products from the mother's diet) for one month. Except for the casein-free diet, the rest of the treatment recommendations will be the same between people.

Main outcome variables

The general conditions of babies based on the mother's understanding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200702047986N2**

Registration date: **2023-04-26, 1402/02/06**

Registration timing: **prospective**

Last update: **2023-04-26, 1402/02/06**

Update count: **0**

Registration date

2023-04-26, 1402/02/06

Registrant information

Name

Davoud Shabani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3367 3149

Email address

davoud9372@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-30, 1402/02/10

Expected recruitment end date

2023-07-22, 1402/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the reduction of infant colic symptoms following casein-free diet in children with and without a history of parental atopy

Public title

Comparison of the reduction of infant colic symptoms following casein-free die

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 15 days to 3 months Having infantile colic

Exclusion criteria:

Lack of parental consent

Age

From **15 days** old to **3 months** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **206**

Randomization (investigator's opinion)

Not randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Arak University of Medical Sciences

Street address

Payambar-e-azam complex, Sardasht Town

City

Arak

Province

Markazi

Postal code

3848176341

Approval date

2023-01-22, 1401/11/02

Ethics committee reference number

IR.ARAKMU.REC.1401.327

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

Infant colic

ICD-10 code

R10.83

ICD-10 code description

Colic

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

The general conditions of babies based on the mother's understanding

Timepoint

Before the start of the intervention and one month after the start of the intervention

Method of measurement

Through a questionnaire that is filled by the mother

Secondary outcomes

empty

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

Intervention group 1: We put 103 breastfed children who have a history of atopy in their parents and referred for the treatment of infant colic under a casein-free diet (removing dairy products from the mother's diet) for one month. Except for the casein-free diet, the rest of the treatment recommendations will be the same between people.

Category

Treatment - Other

2**Description**

Intervention group 2: We put 103 breastfed children who have no history of atopy in their parents and referred for the treatment of infant colic under a casein-free diet (removing dairy products from the mother's diet) for one month. Except for the casein-free diet, the rest of the treatment recommendations will be the same between people.

Category

Treatment - Other

Recruitment centers**1****Recruitment center**

Name of recruitment center

Amirkabir hospital
Full name of responsible person
Roghayeh Ostadi
Street address
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amirkabir-hospital@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mahdi Salehi
Street address
Payambar-e-azam complex, Sardasht Town
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3819693345
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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

Arak 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
Arak University of Medical Sciences
Full name of responsible person

Roghayeh Ostadi
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available