

# 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**  
Shahid Shiroudi St., Parastar Sq.  
**City**  
Arak  
**Province**  
Markazi  
**Postal code**  
3819693181  
**Phone**  
+98 86 3313 4715  
**Email**  
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  
**City**  
Arak  
**Province**  
Markazi  
**Postal code**  
3819693345  
**Phone**  
+98 86 3313 6055  
**Email**  
info@arakmu.ac.ir

#### 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**  
General Practitioner  
**Street address**  
Payambar-e-azam complex, Sardasht Town  
**City**  
Arak  
**Province**  
Markazi  
**Postal code**  
6341738481  
**Phone**  
+98 86 3417 3520  
**Email**  
Ostadi.r.m97@gmail.com

## Person responsible for scientific 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**  
General Practitioner  
**Street address**  
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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
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**Email**

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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