Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

The effect of a diet with low FODMAP (oligosaccharides, disaccharides, monosaccharides and fermentable polyols) in the diet of breastfeeding mothers on the treatment of infantile colic

Protocol summary

Study aim

Finding a way to improve colic in infants, increase the quality of life of families and reduce the additional cost of drugs, by modifying the diet of nursing mothers.

Design

Clinical trial, with two intervention groups and a control group, one blind strain, with a sample size of 110, using block randomization method with 4 blocks

Settings and conduct

In this study, the participants are divided into two groups. The first group (intervention) are mothers who will be under the low FODMAP diet and the second group (control) are mothers who will be under the normal diet during breastfeeding. Both groups will be followed up for two weeks, and the rate of improvement in the colic of their infants will be compared . Blinding is one-way blinding because only the patients are not aware of the type of treatment.

Participants/Inclusion and exclusion criteria

The criteria for entering the study include being a term baby; mother with at least middle school education; exclusive breastfeeding; at least 5 months of age; crying more than 3 hours a day for 3 to more than 3 days a week; not having underlying diseases. The criteria for not entering the study include incomplete completion of the questionnaire and failure to follow the diet correctly by the mother.

Intervention groups

Intervention group: It will include giving special diet for breastfeeding with low FODMAP for two weeks and then checking and comparing it with the control group.
Control group: including giving a special diet during breastfeeding for two weeks without changing its FODMAP content

Main outcome variables

The frequency and average time of breastfeeding of infants; average sleep; the number of times and average time of crying of infants; the number of times of abdominal bloating of infants during 24 hours

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230224057517N1**
Registration date: **2023-04-18, 1402/01/29**
Registration timing: **prospective**

Last update: **2023-04-18, 1402/01/29**
Update count: **0**

Registration date

2023-04-18, 1402/01/29

Registrant information

Name

Reyhaneh Aghaziaraty

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3880 3517

Email address

ziaratyreyhan@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of a diet with low FODMAP (oligosaccharides, disaccharides, monosaccharides and fermentable polyols) in the diet of breastfeeding mothers on the treatment of infantile colic

Public title

The effect of a diet with simple carbohydrates on the treatment of infantile colic

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Term baby (38 to 42 weeks) Mother with at least middle school education Exclusive breastfeeding Age less than 5 months at the time of study Crying more than 3 hours a day for 3 to more than 3 days a week Not suffering from underlying diseases (gastrointestinal tract, kidney, lung, etc.) and not suffering from congenital abnormalities Average family income level

Exclusion criteria:

Non-completion or incomplete completion of the case registration sheet by the mother Failure to follow the correct diet by the mother

Age

To **5 months** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

To assign people to two groups, a block randomization method with a block size of 4 will be used, and by using this method, concealment will be observed. In this method, each person is assigned a unique code.

Blinding (investigator's opinion)

Single blinded

Blinding description

Blinding in this study is one-way blind. In fact , the participants included in this study, despite knowing all the advantages and disadvantages of this study, as well as having full consent and knowledge of participating in this study, have been placed as our blinding groups and are not aware of the type of treatment and study.

Placebo

Not used

Assignment

Parallel

Other design features

The participants in this study are divided into two groups, one (intervention) and two (control) , and the first group receives only one type of intervention during the study. Both groups are subjected to the same conditions during the study and only the first group receives the intervention we are considering.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences، Basij sq.

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2022-11-20, 1401/08/29

Ethics committee reference number

IR.ARAKMU.REC.1401.239

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

Colic recovery status of infants in the Barr scale

Timepoint

The beginning of the study, the seventh day and the fourteenth day after the intervention

Method of measurement

Children's daily behavior measurement scale (Barr scale)

Secondary outcomes

1

Description

The number of feedings of infants in 24 hours

Timepoint

The beginning of the study, the seventh day and the fourteenth day after the intervention

Method of measurement

Children's daily behavior measurement scale (Barr scale)

2

Description

Average 24 hour sleep of infants

Timepoint

The beginning of the study, the seventh day and the fourteenth day after the intervention

Method of measurement

Children's daily behavior measurement scale (Barr scale)

3

Description

Average 24 hours length of crying and fussing

Timepoint

The beginning of the study, the seventh day and the fourteenth day after the intervention

Method of measurement

Children's daily behavior measurement scale (Barr scale)

4

Description

The average feeding time of infants during 24 hours

Timepoint

The beginning of the study, the seventh day and the fourteenth day after the intervention

Method of measurement

Children's daily behavior measurement scale (Barr scale)

5

Description

The number of times infants crying in 24 hours

Timepoint

The beginning of the study, the seventh day and the fourteenth day after the intervention

Method of measurement

Children's daily behavior measurement scale (Barr scale)

6

Description

The number of times infants have flatulence in 24 hours

Timepoint

The beginning of the study, the seventh day and the fourteenth day after the intervention

Method of measurement

Children's daily behavior measurement scale (Barr scale)

Intervention groups

1

Description

Intervention group: The intended intervention will include giving the special diet for breastfeeding with low FODMAP for two weeks to the target group and then checking and comparing it with the control group. The diet considered for mothers will be three main meals, one snack in the morning and one snack in the afternoon. The selection of the ingredients of the food consumed by the mother will be done according to the guidance of the FODMAP database of Monash University, and according to that, a diet plan will be prepared by the nutritionist and will be provided to the participants. It is necessary to mention that the diet recommended to each of the participants is completely diverse, selective and based on the common and widely used foods of families, and only their consumption amount will be variable; In other words, the participants are given the right to choose the type of meal according to their preferences during the day, and families are not required to pay additional fees to comply with their diet.

Category

Other

2

Description

Control group: It will include giving a special diet for breastfeeding for two weeks. The diet considered for mothers will be three main meals, one snack in the morning and one snack in the afternoon. The selection of the ingredients of the food consumed by the mother will be done according to the guidance of the FODMAP database of Monash University, and according to that, a diet plan will be prepared by the nutritionist and will be provided to the participants. It is necessary to mention that the diet recommended to each of the participants is completely diverse, selective and based on the common and widely used foods of families, and only their consumption amount will be variable; In other words, the participants are given the right to choose the type of meal according to their preferences during the day, and families are not required to pay additional fees to comply with their diet.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir Arak Hospital

Full name of responsible person

Sajjadi Nooshin

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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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www.salehi58@gmail.com
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
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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