

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Study of the effect of dairy free diet on irritable bowel syndrome in over 5 year old children

Protocol summary

Study aim

The effect of dairy-free diet on irritable bowel syndrome in children over 5 years

Design

Clinical trial with case and control group, single blind, non-random

Settings and conduct

In order to blind the study, the questionnaire is divided into two groups and the patient is asked to select one group and thus is assigned to one of the case or control groups. The Control group under normal diet and the case groups were exposed to a dairy-free diet for two weeks, including cheese, butter, milk, cream, and other dairy foods, which are one of the triggers for IBS. Finally, the two groups are compared in terms of symptoms.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Informed consent from parents
2.Children over 5 years 3.Have no underlying disease
Exclusion criteria: 1.Children under 5 years 2.Have underlying disease 3.Have a special diet

Intervention groups

Intervention group: Patients with IBS who are on a dairy-free diet for two weeks
Control group: Patients with IBS undergo a regular diet (containing dairy products) for two weeks

Main outcome variables

Significant differences may indicate role of dairy-free diet in symptoms of patients with irritable bowel syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190806044462N1**

Registration date: **2019-09-14, 1398/06/23**

Registration timing: **retrospective**

Last update: **2019-09-14, 1398/06/23**

Update count: **0**

Registration date

2019-09-14, 1398/06/23

Registrant information

Name

ali tabrizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 0099

Email address

a.tabrizi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-06, 1398/05/15

Expected recruitment end date

2019-09-06, 1398/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of dairy free diet on irritable bowel syndrome in over 5 year old children

Public title

Exploring the effect of dairy free diet on irritable bowel syndrome in over 5 year old children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1.Informed consent 2.Children above 5 years Have no underlying disease
Exclusion criteria:
Have a special diet Children under 5 years Have underlying disease

Age

From **5 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **152**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

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

khorm street

City

arak

Province

Markazi

Postal code

0287025012

Approval date

2019-07-10, 1398/04/19

Ethics committee reference number

IR.ARAKMU.REC.1398.104

Health conditions studied

1

Description of health condition studied

irritable bowel syndrome

ICD-10 code

K58.0

ICD-10 code description

Irritable bowel syndrome with diarrhea

Primary outcomes

1

Description

Clinical symptoms of irritable bowel syndrome

Timepoint

Before and 2 weeks after treatment

Method of measurement

Interview with the patient

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with IBS who are on a dairy-free diet for two weeks

Category

Lifestyle

2

Description

Control group: Patients with IBS undergo a regular diet (containing dairy products) for two weeks

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir kabir hospital

Full name of responsible person

dr noushin sajadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

dr noushin sajadi

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Grant name

Grant code / Reference number

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

No

Title of funding source

arak university of medical science

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

dr noushinj sajdadi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data can be shared

When the data will become available and for how**long**

starting 6 months after publication

To whom data/document is available

Public access is free

Under which criteria data/document could be used

No limit

From where data/document is obtainable

dr ali tabrizi email: a.tabrizi@arakmu.ac.ir

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

The data is provided to the applicant within one month

Comments