

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Evaluation of the effect of vitamin E in reducing the duration of treatment in children with gastroenteritis

#### Protocol summary

##### Study aim

Investigating the effect of vitamin E during the treatment of children with gastroenteritis

##### Design

Clinical trial with control and intervention group, without blinding, randomized, phase 2 on 60 patients. Block randomization method is used for randomization

##### Settings and conduct

Based on the inclusion criteria, the people who enter the study are randomly divided into two groups receiving vitamin E for 10 days and standard treatment (liquid therapy and ORS) and a group of patients who only receive standard gastroenteritis treatment. The duration of the disease is based on the clinical symptoms of gastroenteritis. The obtained results are recorded in the checklist prepared for this purpose. Also, this study is conducted by project managers and relevant interns. In this study, randomization, selection of patients, allocation of patients to groups in this study is done by the student himself. In addition to these drugs, the relevant doctor who is the main guide will be prescribed.

##### Participants/Inclusion and exclusion criteria

All children aged 1-13 years with acute gastroenteritis referred to Amirkabir Hospital, whose acute gastroenteritis was confirmed by a pediatric specialist based on the symptoms of diarrhea, vomiting, abdominal pain and dehydration. and have informed consent to participate in the study

##### Intervention groups

In addition to the routine treatment with fluid therapy, the intervention group will receive the standard daily amount of vitamin E drops from Besa company for 10 days according to the age.

##### Main outcome variables

The duration of the disease is based on the clinical symptoms of gastroenteritis, which include Diarrhea, vomiting, abdominal pain, fever and dehydration which are assessed at the beginning and end of the study

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20231119060105N1**

Registration date: **2023-11-25, 1402/09/04**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-11-25, 1402/09/04**

Update count: **0**

##### Registration date

2023-11-25, 1402/09/04

##### Registrant information

##### Name

Zeinab Saleh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3313 6555

##### Email address

z.saleh.g@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-10-01, 1402/07/09

##### Expected recruitment end date

2024-05-29, 1403/03/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of vitamin E in reducing the duration of treatment in children with gastroenteritis

### Public title

Evaluation of the effect of vitamin E in reducing the duration of treatment in children with gastroenteritis

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

All children aged 1-13 years with acute gastroenteritis referred to Amirkabir Hospital, whose acute gastroenteritis was confirmed by a pediatric specialist based on the symptoms of diarrhea, vomiting, abdominal pain and dehydration. Informed consent to participate in the study

#### Exclusion criteria:

Children who cannot tolerate oral vitamin E People who do not cooperate.

### Age

From **1 year** old to **13 years** old

### Gender

Both

### Phase

2

### Groups that have been masked

*No information*

### Sample size

Target sample size: **60**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Block randomization will be done, for this purpose, the participants will be assigned to two intervention and control groups according to the order of arrival and based on the randomization sequence that will be generated in advance. This sequence is unpredictable and its arrangement is completely random. . Block randomization method with 8 blocks will be used to allocate the samples. In this way, using the site [www.sealedenvelope.com](http://www.sealedenvelope.com), blocks of 8 letters A and B are randomly generated based on the sample size. The order of placement of letters A and B in each block from the first block to the last block is considered as a randomization sequence. The production of these blocks and their random sequence is completely done by this site and the researcher does not know how they are sequenced.

### 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

Arak University of medical science, Basij square

##### City

Arak

##### Province

Markazi

##### Postal code

8735610954

#### Approval date

2023-09-30, 1402/07/08

#### Ethics committee reference number

IR.ARAKMU.REC.1402.164

## Health conditions studied

### 1

#### Description of health condition studied

gastroenteritis

#### ICD-10 code

A09

#### ICD-10 code description

Infectious gastroenteritis and colitis, unspecified

## Primary outcomes

### 1

#### Description

The effect of vitamin E on reducing the duration of diarrhea, vomiting, abdominal pain, fever, anorexia and dehydration in gastroenteritis patients.

#### Timepoint

The beginning of the intervention and the end of symptoms

#### Method of measurement

Through history and questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: intervention group In addition to routine treatment, which includes fluid therapy and ORS, receive vitamin E drops from "Bahsa" company, each milliliter of which contains 10 international units of vitamin E, for 10 days according to age as follows We use: age 1-3 years: 18 drops equal to 0.90 ml; Age 4-8 years: 21 drops equal to 1.05 ml; Age 9-13 years: 33

drops equal to 1.65 ml

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Amirkabir hospital

**Full name of responsible person**

Dr. Ali Arjmand

**Street address**

Shahid Shiroudi St. - Nurse Square - Amirkabir Hospital

**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**

Mehdi Salehi

**Street address**

Arak University of medical science, Basij square

**City**

Arak

**Province**

Markazi

**Postal code**

8735610954

**Phone**

+98 86 3417 3522

**Email**

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****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr. Ali Arjmand

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Pediatrics

**Street address**

Shahid Shiroudi St. - Nurse Square - Amirkabir Arak Hospital

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**Province**

Markazi

**Postal code**

3819693181

**Phone**

+98 86 3313 4715

**Email**

Aliarjmand1@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr. Ali Arjmand

**Position**

Associate professor

**Latest degree**

Specialist

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr. Ali Arjmand

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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**

All data can potentially be shared after de-identifying individuals

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

The access period starts 6 months after the results are published

**To whom data/document is available**

Researchers working in academic and scientific institutions, as well as people working in the industry, can apply for them

**Under which criteria data/document could be used**

There are no other conditions

**From where data/document is obtainable**

To the main person responsible for the study; Dr. Ali Arjmand can be contacted at Aliarjmand1@yahoo.com

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

The applicant can contact the person in charge of the study through the email address and get access to the information as soon as possible after the request

**Comments**