# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

30 Jul 2026

## The effects of arginine supplementation on clinical symptoms, quality of life and anal internal sphincter pressure in patients with chronic anal fissure

## Protocol summary

**Study aim**
Determination of the effect of arginine supplementation on clinical signs, quality of life and internal anal sphincter pressure in patients with chronic anal fissure

**Design**
a randomized, double-blind, placebo-control clinical trial with two arms parallel study design

**Settings and conduct**
The study will be conducted in the first and second semester of 1398 for adults with chronic anal fissures referred to the gastroenterology clinic of Rasoul-e-Akram Hospital. Eligible individuals after filling written informed consent are randomly divided into two groups that received arginine or placebo. Patients and researchers will be blinded to the interventions. Demographic data, the severity of clinical symptoms, quality of life, stress and anxiety, manometry, physical activity, diet, and anthropometric indexes were evaluated at the beginning and the end of the study.

**Participants/Inclusion and exclusion criteria**
1. Age between 18 to 65 years 2. BMI between 18.5 to 35 3. Chronic anal fissure 4. Fischer in the posterior and anterior regions of the anus. 5. Non-pregnant and lactating women 6. Non-specific digestive disease, such as Crohn's disease, ulcerative colitis, gastrointestinal cancers and etc. 7. without any diseases that fissure can be their complication: tuberculosis, AIDS, syphilis, herpes, leukemia and etc. 8. No history of malignancy or malignancy in present 9. No history of heart disease 10. No history of fissure and hemorrhoid surgery

**Intervention groups**
Patients with chronic anal fissure will divide into two groups that receive the arginine and the placebo. 90 supplements will be taken by patients 3 times a day for 1 month.

**Main outcome variables**
Clinical symptoms Quality of Life Reduce internal anal sphincter pressure

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20190712044182N1**
Registration date: **2019-08-27, 1398/06/05**
Registration timing: **registered_while_recruiting**

Last update: **2019-08-27, 1398/06/05**
Update count: **0**

**Registration date**
2019-08-27, 1398/06/05

**Registrant information**

**Name**
Mohsen Masoodi

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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+98 21 6655 4790

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2019-07-28, 1398/05/06

**Expected recruitment end date**
2020-01-26, 1398/11/06

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
The effects of arginine supplementation on clinical symptoms, quality of life and anal internal sphincter pressure in patients with chronic anal fissure

**Public title**
Effect of arginine on chronic anal fissure

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Chronic Anal Fischer Fisher in the posterior and anterior areas of the anus Non-pregnant and lactating women Age: 18 - 65 years BMI: 18.5 - 35 kg/m2 Non-specific digestive diseases such as Crohn's disease, Ulcerative colitis, gastrointestinal cancers and etc. The absence of diseases that fissure can be their complications: tuberculosis, AIDS, syphilis, herpes, leukemia and etc. No history of malignancy or malignancy in present No history of heart disease No history of fissure and hemorrhoid surgery

**Exclusion criteria:**

**Age**
From **18 years** old to **65 years** old

**Gender**
Both

**Phase**
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **76**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
For randomization, the permuted block randomization will be used with quadrilateral blocks. According to the sample size of 76 that has been set, 19 blocks will be produced by using the online site "www.sealedenvelope.com". In order to apply the concealment in the randomization process, unique codes will be used on supplement boxes, the code being generated by the software. By entering each individual into a study based on the generated sequence, the supplement package with the specific code will be allocated to the individual, and therefore, before the person is selected, nobody aware of the type of treatment he will receive.

**Blinding (investigator's opinion)**
Triple blinded

**Blinding description**
In this study, participants, researchers, evaluators of the outcomes, and data analyzers will be blinde to the type of intervention.

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics committee of Iran University of Medical Sciences

**Street address**
Iran University of Medical Sciences, next to Milad Tower, Hemat highway

**City**
Tehran

**Province**
Tehran

**Postal code**
14665354

**Approval date**
2019-06-16, 1398/03/26

**Ethics committee reference number**
IR.IUMS.REC.1398.319

## Health conditions studied

### 1

**Description of health condition studied**
chronic anal fissure

**ICD-10 code**
K60.1

**ICD-10 code description**
Chronic anal fissure

## Primary outcomes

### 1

**Description**
Clinical symptoms (bleeding)

**Timepoint**
at the beginning and the end of the study

**Method of measurement**
Visual Analogue Scale

### 2

**Description**
Clinical symptoms (pain)

**Timepoint**
at the beginning and the end of the study

**Method of measurement**
Visual Analogue Scale

### 3

**Description**
Clinical symptoms (improve ulcer )
**Timepoint**
at the beginning and the end of the study
**Method of measurement**
Visual Analogue Scale

## Secondary outcomes

### 1

**Description**
Quality of life
**Timepoint**
at the beginning and end of the study
**Method of measurement**
General Health Survey Short Form-36

### 2

**Description**
Internal anal sphincter pressure
**Timepoint**
at the beginning and end of the study
**Method of measurement**
manometry

## Intervention groups

### 1

**Description**
Intervention group: L-arginine supplement, manufactured by Karen Company, 90 capsules consumed 3 times daily (3 grams of arginine per day) with their meals for one month.
**Category**
Treatment - Other

### 2

**Description**
Control group: placebo manufactured by Karen Company, 90 capsules consumed 3 times daily with their meals for one month.
**Category**
Placebo

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Rasoul-e-Akram hospital
**Full name of responsible person**
Mohsen Masoodi
**Street address**
Rasoul-e-Akram hospital, Maziar Mansouri Ave., Sattarkhan Street
**City**
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Iran University of Medical Sciences
**Full name of responsible person**
Mohsen Masoodi
**Street address**
Colorectal Research Center, Rasoul-e-Akram Hospital, Maziar Mansouri St., Sattarkhan St.
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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**
Iran 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**
Iran University of Medical Sciences
**Full name of responsible person**
Masoumeh Khalighi Sikaroudi
**Position**
Master of Science
**Latest degree**

Master

**Other areas of specialty/work**
Nutrition

**Street address**
Colorectal Research Center, Rasoul-e-Akram Hospital, Maziar Mansouri St., Sattarkhan St.

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Email**
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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**
No - There is not a plan to make this available

**Title and more details about the data/document**
Information about the main consequences will be shared.

**When the data will become available and for how long**
Start the access period, 6 months after publication of results

**To whom data/document is available**
Physicians, nutritionist, patients with anal fissure and constipation

**Under which criteria data/document could be used**
Published as an article

**From where data/document is obtainable**
Masoumeh Khalighi Sikaroudi gmail adress: masoomehkhalighi@gmail.com

**What processes are involved for a request to access data/document**
mail will be sent to the main author or co-response, and in less than 1 week, the available data will send to the individual.

**Comments**