

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)

Phone

+98 21 6655 4790

Email address

masoodi.m@iums.ac.ir

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

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1445613131

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Email

crrc.iums@gmail.com

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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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:
masoomehkhalthighi@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