

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### The Effectiveness of probiotic in the treatment of gastrointestinal symptoms in patients with scleroderma

#### Protocol summary

##### Summary

The aim of this study was to evaluate effectiveness of probiotic in the treatment of gastrointestinal symptoms in patients with scleroderma who referred to Imam Khomeini hospital in 2014. In this clinical trial, 37 patients with systemic sclerosis with moderate to severe symptoms were divided randomly in two intervention and control groups. The probiotic was given to intervention group and placebo to control group which similar to probiotic. Inventory (UCLA SCTC GIT 2.0) was used for rating the severity of the gastrointestinal tract. The efficacy of probiotic in treatment of gastrointestinal symptoms was measured.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015120618142N2**

Registration date: **2015-12-25, 1394/10/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-12-25, 1394/10/04

##### Registrant information

##### Name

Firouz Amani

##### Name of organization / entity

Ardabil University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 45 1551 3777

##### Email address

f.amani@arums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2014-04-30, 1393/02/10

##### Expected recruitment end date

2014-07-01, 1393/04/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effectiveness of probiotic in the treatment of gastrointestinal symptoms in patients with scleroderma

##### Public title

The Effectiveness of probiotic in the treatment of gastrointestinal symptoms in patients with scleroderma

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: patients with gastrointestinal symptoms moderate to severe Exclusion criteria: non using drug in exact time; non tolerance for drug side effects; non tended to participate in study

##### Age

From **18 years** old to **57 years** old

##### Gender

Both

##### Phase

N/A

##### Groups that have been masked

*No information*

##### Sample size

Target sample size: **37**

##### Randomization (investigator's opinion)

Randomized  
**Randomization description**  
**Blinding (investigator's opinion)**  
Double blinded  
**Blinding description**  
**Placebo**  
Used  
**Assignment**  
Parallel  
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**  
**Name of ethics committee**  
Tehran University of Medical Sciences  
**Street address**  
Tehran University of Medical Sciences, Tehran  
**City**  
Tehran  
**Postal code**  
**Approval date**  
2013-09-23, 1392/07/01  
**Ethics committee reference number**  
921128800

## Health conditions studied

### 1

**Description of health condition studied**  
scleroderma  
**ICD-10 code**  
M34  
**ICD-10 code description**  
Systemic sclerosis

## Primary outcomes

### 1

**Description**  
Improvement in gastrointestinal symptoms  
**Timepoint**  
Baseline-two month late  
**Method of measurement**  
Score

## Secondary outcomes

### 1

**Description**  
Improvement in reflux condition , emotional and social function

**Timepoint**  
baseline-after two months  
**Method of measurement**  
Score

## Intervention groups

### 1

**Description**  
Intervention group: Probiotics use in form of drug pill  
**Category**  
Placebo

### 2

**Description**  
control: placebo similar to main drug  
**Category**  
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**  
**Name of recruitment center**  
Romatology clinic of Imam Khomeini hospital  
**Full name of responsible person**  
Shafieh Movassaghi  
**Street address**  
Imam Khomeini hospital-Bolvar Keshavarz-Tehran  
**City**  
Tehran

## Sponsors / Funding sources

### 1

**Sponsor**  
**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Shahin Akhonzadeh Basti  
**Street address**  
Faculty of medicine,Tehran University of Medical Sciences,Enghelab Avenue-Tehran  
**City**  
Tehran  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Tehran University of Medical Sciences  
**Proportion provided by this source**  
100  
**Public or private sector**  
empty  
**Domestic or foreign origin**  
empty

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

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

Ardabil University of Medical Sciences

**Full name of responsible person**

Dr. Afsaneh Enteshari-Moghaddam

**Position**

Assistant professor

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**Full name of responsible person**

Dr. Afsaneh Enteshari-Moghaddam

**Position**

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**Other areas of specialty/work****Street address**

Ardabil University of Medical Sciences

**City**

Ardabil

**Postal code****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*