Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Effectivness 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 Univesity of Medical Science

Country

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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 Effectivness of probiotic in the treatment of gastrointestinal symptoms in patients with scleroderma

Public title

The Effectivness 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 sever 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
Improvment 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
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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