

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of synbiotic supplementation on disease activity, Th17 cells frequency, IL-23/IL-17 axis expression and serum levels of IL-17 and IL-23 in patients with ankylosing spondylitis

Protocol summary

Study aim

Determining the effect of synbiotic supplement on disease activity, Th17 frequency, IL-23/IL-17 axis expression and serum IL-17 and IL-23 levels in ankylosing spondylitis patients

Design

Clinical trial with control group, parallel groups, double blind, randomized

Settings and conduct

48 AS patients referred to rheumatology clinic are selected based on inclusion and exclusion criteria. Patients will be randomly divided into two groups receiving synbiotic (24) and receiving placebo (24). The study groups will receive one synbiotic capsule (zist-takhmir company) or placebo per day for 3 months. Participants and outcome assessors will be blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: willing to participate; age range 20-60 years; diagnosis of AS by a rheumatologist Exclusion criteria: using nutritional and antioxidant supplements during one month prior to the study; pregnancy and lactation; history of having other autoimmune diseases; history of having diabetes and inflammatory bowel diseases; gastrointestinal system infections; recurrence of disease during the study

Intervention groups

Intervention group: receiving one synbiotic capsule per day for 3 months Placebo group: receiving one placebo capsule per day for 3 months

Main outcome variables

disease activity; Th17 cells frequency; IL-23/IL-17 axis expression; serum IL-17 and IL-23 levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190917044794N1**

Registration date: **2019-09-28, 1398/07/06**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-28, 1398/07/06**

Update count: **0**

Registration date

2019-09-28, 1398/07/06

Registrant information

Name

Aida Malek Mahdavi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3336 9331

Email address

amalek@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of synbiotic supplementation on disease activity, Th17 cells frequency, IL-23/IL-17 axis expression and

serum levels of IL-17 and IL-23 in patients with ankylosing spondylitis	
Public title	Effect of synbiotic supplementation in ankylosing spondylitis
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Willing to participate Age range 20-60 years AS diagnosis by rheumatologist Exclusion criteria: Taking nutritional and antioxidant supplements one month prior to study Pregnancy and lactation History of other autoimmune diseases History of diabetes mellitus, IBD Gastrointestinal infection and other chronic diseases The recurrence of the disease during the study Unwilling to continue the study
Age	From 20 years old to 60 years old
Gender	Both
Phase	N/A
Groups that have been masked	• Participant • Care provider • Investigator
Sample size	Target sample size: 48
Randomization (investigator's opinion)	Randomized
Randomization description	The selected samples will be randomly (block randomization) divided into two groups: synbiotic and placebo.
Blinding (investigator's opinion)	Double blinded
Blinding description	Participants, care provider and investigator will be blind in this study. The way of participant blindness is that he will receive and use a certain number of drugs in an unnamed and labeled envelope. The way of care provider blindness is that after making diagnosis of ankylosing spondylitis to his patient and notifying his secretary, randomly gives one of the envelopes to the patient. The way of researcher's blindness is that he will not be present in the filling envelopes and selecting them by secretary.
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of medical Sciences

Street address

Golgasht St.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614754

Approval date

2019-08-19, 1398/05/28

Ethics committee reference number

IR.TBZMED.REC.1398.591

Health conditions studied

1

Description of health condition studied

Ankylosing spondylitis

ICD-10 code

M45

ICD-10 code description

Ankylosing spondylitis

Primary outcomes

1

Description

disease activity

Timepoint

Before and after intervention

Method of measurement

BASDAI and BASFI criteria

2

Description

Th17 cells frequency

Timepoint

Before and after intervention

Method of measurement

Flow cytometry

3

Description

IL-23/IL-17 axis expression

Timepoint

Before and after intervention

Method of measurement

Real-time PCR and ELISA

4

Description

Serum IL-17 cytokine

Timepoint

Before and after intervention

Method of measurement

ELISA kit

5

Description

Serum IL-23 cytokine

Timepoint

Before and after intervention

Method of measurement

ELISA kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 1 synbiotic capsule fami lact per day for 3 months from Zist Takhmir factory capsules include: 10⁹ CFU bacteria namely *Lactobacillus casei*, *Lactobacillus Ramnosis*, *Lactobacillus acidophilus*, *Lactobacillus bolgaricus*, *streptococcus thermophilus*, *bifidobacterium Langom* and *fructooligosacharide (FOS)* prebiotic

Category

Treatment - Other

2

Description

Placebo group: 1 placebo capsule per day including corn starch from Zist Takhmir factory for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Imam-Reza Hospital

Full name of responsible person

Masoud Ahangari Maleki

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Samiei

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Samiei.moh@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Aida Malek Mahdavi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

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Tabriz University of Medical Sciences
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Abuse is possible.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable