

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Investigating the Effect of Synbiotic Supplementation and educating low-calorie diet on the Lipid Profile and the Gut Micro-flora in Patients with Metabolic Syndrome

Protocol summary

Summary

Investigating the Effect of Synbiotic Supplementation and educating low-calorie diet on the Lipid Profile and the Gut Micro-flora in Patients with Metabolic Syndrome The study will be conducted as a double-blind randomized controlled trial with the standard placebo. The required sample size for this study, considering the 20% probability of subject missing, will be 66 subjects for each groups and 132 subjects in total. All the subjects will be taught low-calorie diet, then subjects randomly will be divided into the two groups of receiving synbiotic or standard placebo. All of the procedures will be conducted double-blind to the researcher and patients alike and in supervision of a third person. The intervention will be done for 12 weeks. Regarding the results of previous human studies conducted on synbiotic, consumption of these capsules will not have any side effects for patients. Patients who have at least 3 criteria of all of 5 criteria of Metabolic Syndrome provided that not taking medication for controlling Blood Glucose, Blood Lipid and Hypertension will be included into the study. In case of losing any of including criteria or having to taking any of mentioned medications, the patient will be excluded from the study. The main outcomes expected to be affected by the interventions, will be include: dysbiosis modifying; increase in High-Density Lipoprotein-Cholesterol (HDL-C); decrease in Low-density Lipoprotein- Cholesterol (LDL), Triglycerides, Blood Pressure and Waist Circumference.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201608299856N3**
Registration date: **2017-02-07, 1395/11/19**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-02-07, 1395/11/19

Registrant information

Name

Yahya Pasdar

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1828 1991

Email address

yahya.pasdar@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

1. Deputy of Research and Technology, Kermanshah University of Medical Sciences 2. ZistTakhmir Pharmaceutical Company

Expected recruitment start date

2016-10-06, 1395/07/15

Expected recruitment end date

2016-12-05, 1395/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effect of Synbiotic Supplementation and educating low-calorie diet on the Lipid Profile and the Gut Micro-flora in Patients with Metabolic Syndrome

Public title

The Effect of Synbiotic Supplementation on Metabolic Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Filling the consent form of the present project in the beginning of study; lack of any kinds of chronic diseases such as diabetes, renal diseases, tuberculosis, liver diseases and/or the history of cardiac surgeries; possessing at least 3 items of all the 5 indexes of metabolic syndrome (based on the definition by NCEP ATP III) (in case of insulin resistance, patients must have fasting blood glucose less than 126 mg/dL); lack of taking medication to control blood glucose, blood lipid and hypertension in the beginning of study ; the age range is between 25 to 65 year; lack of injecting/receiving insulin so as to blood glucose control in the beginning of study. Exclusion criteria: Lack of regular taking the given supplements; lack of following the given diet; starting taking medication or supplements that may be affect the results of test of investigated factors or oral contraceptives, estrogen, progesterone and corticosteroids; pregnancy; weaning, receiving insulin or tablet to control the blood glucose; losing any of inclusion criteria during the time of conducting the study.

Age

From **24 years** old to **64 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **132**

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**

Kermanshah University of Medical Sciences Ethics Committee

Street address

Deputy of Research and Technology, Building No. 2 of Kermanshah University of Medical Sciences, Naft Square, Shahid Beheshti blvd

City

Kermanshah

Postal code**Approval date**

2016-10-19, 1395/07/28

Ethics committee reference number

kums.rec.1395.467

Health conditions studied**1****Description of health condition studied**

Hypertension

ICD-10 code

I15.9

ICD-10 code description

Secondary hypertension, unspecified

2**Description of health condition studied**

Hyperglyceridaemia

ICD-10 code

E78.1

ICD-10 code description

Pure hyperglyceridaemia

3**Description of health condition studied**

High-density lipoprotein deficiency

ICD-10 code

E78.6

ICD-10 code description

Lipoprotein deficiency

Primary outcomes**1****Description**

blood pressure

Timepoint

base line, at the end of 6th week and aftar 3 months of begin

Method of measurement

in term of mm Hg by Mercury barometers

2**Description**

plasma HDL-C

Timepoint

base line and aftar 3 months of begin

Method of measurement

in term of mg/ dL by biochemical kits

3

Description

plasma TG

Timepoint

base line and after 3 months of begin

Method of measurement

in term of mg/ dL by biochemical kits

4

Description

Waist Circumference

Timepoint

base line, at the end of 6th week and after 3 months of begin

Method of measurement

in term of centimeter by Tape measure

Secondary outcomes

1

Description

LDL-C

Timepoint

baseline and after 3th month

Method of measurement

in term of mg/ dL, by using biochemical kits

2

Description

Total Cholesterol

Timepoint

baseline and after 3th month

Method of measurement

in term of mg/ dL, by using biochemical kits

3

Description

Body Fat Mass

Timepoint

baseline, at the end of 6th week and after 3th month

Method of measurement

in term of kg, by usig body analyzer instrument

4

Description

Body Fat Free Mass

Timepoint

baseline, at the end of 6th week and after 3th month

Method of measurement

in term of kg, by usig body analyser instrument

5

Description

Body Mass Index (BMI)

Timepoint

baseline, at the end of 6th week and after 3th month

Method of measurement

in term of kg/ m2

6

Description

weight

Timepoint

baseline, at the end of 6th week and after 3th month

Method of measurement

in term of kg by using standardized scale

Intervention groups

1

Description

for control group: Standardized Placebo, quite similar to synbiotic capsules, twice/day by oral , for 3 months; Additionally, training low calorie diet will be taught for this group in baseline and in the end of 6th week.

Category

Placebo

2

Description

for intervention group: Synbiotic Dietary Supplement, 500 mg capsule, twice/day by oral, for 3 months; Additionally, training low calorie diet will be taught for this group in baseline and in the end of 6th week.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Administration of Education

Full name of responsible person

Ms.Nazari

Street address

Phase1, Farhangian, next to the Moalem Park

City

Kermanshah

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice - Chancellery of Research & Technology Affairs of Kermanshah University of Medical Sciences

Full name of responsible person

Kourosh Hamzehee

Street address

Vice- Chancellery of Research & Technology Affairs, Building No. 2 of Kermanshah University of Medical Sciences, Naft Square, Shahid Beheshti blvd

City
Kermanshah

Grant name

Grant code / Reference number

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

Title of funding source
Vice – Chancellery of Research & Technology Affairs of Kermanshah University of Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity
ZistTakhmir Pharmaceutical Company

Full name of responsible person
Dr Negin Zand

Street address
No.597, preceding Heidarkhani crossroads, Farjam Gharbi St., Resalat square, Tehran.

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
ZistTakhmir Pharmaceutical Company

Proportion provided by this source

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
Public Health faculty of Kermanshah University of Medical Sciences

Full name of responsible person
Fateme Rahimi

Position
MS.c student in Nutrition Sciences/chief cooperater of plan

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity
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Position
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Other areas of specialty/work

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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