Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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 aftar 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 aftar 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
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Fateme Rahimi
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Web page address

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