Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Oct 2026

The Effects of Synbiotic and lactic acid in beta glucan based bread on Glycemic Control،Blood Lipid Profile, and Antioxidant Capacity in Patients with type 2 diabetes

Protocol summary

Summary

The goal of this study is the evaluation of the effects of synbiotics and lactic acid in betaglucan based bread on lipid profile , glucose index and antioxidant indices of type 2 dibetic patients. with age between 20-60 years without any heart,renal,hepatic or infectious diseases who refer to endocrine research centre.100 patients participate in 4 groups:lactic acid containing bread ,synbiotic containing bread,synbiotic+lactic acid containing bread,betaglucan based bread.The duration of intervention is 8 weeks.Patient's blood sample is taken before and after the intervention.The questionare about personal information,physical activity and recall diet is comleted by experts.Anthropometric measurment include height,weight,waist circumference and blood pressure is done based on standard .The bread formulation is determined based on previous study and food science consult.This study is double blind ,both reasearcher and patient don t know about the type of bread.biochemical assessments is performed for blood sample.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201505242709N33**
Registration date: **2015-11-23, 1394/09/02**
Registration timing: **na**

Last update:
Update count: **0**

Registration date

2015-11-23, 1394/09/02

Registrant information

Name

Farzad Shidfar

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8862 2755

Email address

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Recruitment status

Not enough for processing

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2016-01-05, 1394/10/15

Expected recruitment end date

2015-10-23, 1394/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of Synbiotic and lactic acid in beta glucan based bread on Glycemic Control،Blood Lipid Profile, and Antioxidant Capacity in Patients with type 2 diabetes

Public title

Effects of synbiotic bread containing lactic acid on type2 diabetes

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria:age20-60years;lack of insulin consuming;FBS more than or equal to 126 mg/dl;glycosylated hemoglubin more than 6.5 percent;no

consumption of any drug except drugs for control of blood glucose;no gestational diabetes;willingness to cooperate. exclusion criteria:history of metabolic diseases,cardiovascular disease,renal disease,tyroid ,cancer ;treatment with blood lipid affecting medications in the process of intervention;infectious diseases;gluten sensitive;smoking.

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

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
Iran University of Medical Sciences

Street address
Iran University of Medical sciences

City
Tehran

Postal code

Approval date
2015-09-22, 1394/06/31

Ethics committee reference number
IR.IUMS.REC.1394.26524

Health conditions studied

1

Description of health condition studied
Assessment of health problem status

ICD-10 code
E11

ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
A1c glycosilated hemoglubin

Timepoint
before and after the intervention

Method of measurement
brinnate affinity

2

Description
total cholestrol

Timepoint
before and after the intervention

Method of measurement
autoanalyzer

3

Description
fasting blood sugar

Timepoint
before and after the intervention

Method of measurement
autoanalyzer

4

Description
Triglyceride

Timepoint
before and after the intervention

Method of measurement
autoanalyzer

5

Description
low density lipopritein

Timepoint
before and after the intervention

Method of measurement
autoanalyzer

6

Description
high density lipoprotein

Timepoint
before and after the intervention

Method of measurement
autoanalyzer

7

Description
insulin

Timepoint
before and after the intervention

Method of measurement

radioimmunoassay

8

Description
ApoA1
Timepoint
before and after the intervention
Method of measurement
immunotorbidometri

9

Description
ApoB100
Timepoint
before and after the intervention
Method of measurement
immunotorbidometri

10

Description
ALT
Timepoint
before and after the intervention
Method of measurement
spectrophotometri

11

Description
AST
Timepoint
before and after the intervention
Method of measurement
spectrophotometri

12

Description
ALP
Timepoint
before and after the intervention
Method of measurement
spectrophotometri

13

Description
TAC
Timepoint
before and after the intervention
Method of measurement
FRAP

14

Description
superoxide dismutase
Timepoint
before and after the intervention
Method of measurement
FRAP

15

Description
glutation peroxidase
Timepoint
before and after the intervention
Method of measurement
FRAP

Secondary outcomes

1

Description
Dietary intake
Timepoint
before intervention, 2 month after intervention
Method of measurement
questionnaire

2

Description
weight
Timepoint
before and after the intervention
Method of measurement
digital balance

3

Description
body mass index
Timepoint
before and after the intervention
Method of measurement
weight divides on the square of the height

4

Description
physical activity
Timepoint
before and after the intervention
Method of measurement
international physical activity questionarre

5

Description
blood pressure
Timepoint
before and after the intervention
Method of measurement
digital barometer

Intervention groups

1

Description
betea glucan bread (control group) 3g/day
Category

N/A

2

Description
betaglucan bread containing synbiotic (fructo oligosacaride and bacillus coagulance) bciluse coagullance :18cfu/gram fructo oligo saccaride:10gram/day
Category
Other

3

Description
betaglucan based bread containing synbiotic +acid lactic
Category
Treatment - Drugs

4

Description
betaglucan based bread containing lactic asid lactic acid :4.4gram per kilogram of bread
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
National Iranian Tanker Company
Full name of responsible person
Farzad Shidfar
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences, Occupational Health Research Center
Full name of responsible person
Farzad Shidfar
Street address
Cross road of Shaheed Hemat and Chamran highway, Iran University of Medical Sciences
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University of Medical Sciences, Occupational Health Research Center
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
Iran University of Medical Scinces
Full name of responsible person
Farzad Shidfar
Position
PhD in Nutrition
Other areas of specialty/work
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master degree

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