

# 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 betaglucon 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,betaglucon based bread.The duration of intervention is 8 weeks.Patient's blood sample is taken before and after the intervention.The questionnaire about personal information,physical activity and recall diet is completed 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

shidfar.f@iums.ac.ir

##### 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 hemoglobin 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,thyroid ,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 hemoglobin

#### 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 lipoprotein

#### 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**

immunoturbidometri

## 9

### **Description**

ApoB100

### **Timepoint**

before and after the intervention

### **Method of measurement**

immunoturbidometri

## 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**

glutathione 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 questionnaire

## 5

### **Description**

blood pressure

### **Timepoint**

before and after the intervention

### **Method of measurement**

digital barometer

## **Intervention groups**

## 1

### **Description**

beta glucan bread (control group) 3g/day

### **Category**

N/A

## 2

### Description

betaglucon bread containing synbiotic (fructo oligosaccharide and bacillus coagulance) bciluse  
coagullance :18cfu/gram fructo oligo  
saccaride:10gram/day

### Category

Other

## 3

### Description

betaglucon based bread containing synbiotic +acid lactic

### Category

Treatment - Drugs

## 4

### Description

betaglucon 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

#### Street address

Cross road of Shaheed Hemat and Chamran highway,  
Iran University of Medical Sciences

#### City

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#### Postal code

#### Phone

+98 21 8670 4638

#### Fax

#### Email

farzadshidfar@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Farzad Shidfar

#### Position

PhD in Nutrition

#### Other areas of specialty/work

#### Street address

Cross road of Shaheed Hemat and Chamran highway,  
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## Person responsible for updating data

### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Atie Ghafouri

**Position**

master degree

**Other areas of specialty/work****Street address**

Tehran

**City**

Tehran

**Postal code**

#

**Phone**

+98 21 2289 2494

**Fax****Email**

atie.ghafouri@yahoo.com

**Web page address**

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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*