

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Effect of soybean flour enriched bread consumption or usual dietary recommendation on serum levels of inflammatory bio markers, lipid profile, glycemic indices and Anthropometric indices in patients with type 2 diabetes: a randomized controlled trial

#### Protocol summary

##### Summary

Design: cross-over clinical trial. Participants: Type 2 diabetic women. The objective: Evaluation the impact of soybean flour enriched bread consumption on serum levels of inflammatory bio markers, lipid profile, glycemic indices and Anthropometric indices in type 2 diabetic women. Inclusion criteria: Type 2 diabetic women, lack of insulin injection. Exclusion criteria: menopause, use of multivitamin and mineral supplementation. Setting and conduct: After a 2 week run-in period, participants will be randomly assigned to soybean flour enriched bread and recommendation group each for 6 weeks. After the first phase of intervention, a 4-week washout period will be applied. Then the participants will be crossed over to the alternate group for additional 6 weeks. To assess the compliance of the participants, we will assess dietary intakes of subjects by the use of dietary records once in every two weeks. Physical activity levels will also be assessed by a physical activity record once in every two weeks. biochemical assessments of inflammatory bio markers including high sensitivity C-Reactive Protein (hs-CRP), serum inter-cellular adhesion molecule (sICAM-1), serum vascular cell adhesion molecule (sVCAM-1), high sensitive interleukin 6 (hs IL-6) and high sensitive tumor necrosis factor-alpha (hs TNF- $\alpha$ ) will be measured at the beginning and end of each phases. Appropriate statistical methods will be applied for data analyses. usual dietary recommendation includes healthy food choices. participants in the intervention group will be asked to replace 120 gr of soy bread with the equal amount of their usual bread intake.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013061613684N1**

Registration date: **2013-08-18, 1392/05/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-08-18, 1392/05/27

##### Registrant information

###### Name

Asma Salarimoghaddam

###### Name of organization / entity

Isfahan University Of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 1792 2752

###### Email address

salarimoghaddam@hlth.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

##### Expected recruitment start date

2012-12-07, 1391/09/17

##### Expected recruitment end date

2013-02-05, 1391/11/17

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Effect of soybean flour enriched bread consumption or usual dietary recommendation on serum levels of inflammatory bio markers, lipid profile, glycemic indices and Anthropometric indices in patients with type 2 diabetes: a randomized controlled trial

## Public title

Effect of soybean flour enriched bread consumption on inflammation, lipid profile, glycemic indices and Anthropometric indices

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Diabetic non menopause; non-pregnant and non-lactating females; aged 30-50 y; body mass index greater than 25; Lack of insulin injection; non-smokers; lack of allergy to soyabean; lack of having a special diet; lack of severe weight loss in the last 3 months; lack of hormone therapy; not having severe infection in the last 3 months; trauma; surgery; hypo- and hyper-thyroidism; vitamin and mineral supplements; and corticosteroids. Exclusion criteria: affecting by the above-mentioned diseases or starting the use of above-mentioned medications; alterations in dosage and type of current medications; getting pregnant; allergy to soyabean; the use of medications and supplements such as multivitamin mineral supplementation; omega-3 fatty acids; smoking

## Age

From **30 years** old to **50 years** old

## Gender

Female

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **30**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Crossover

## Other design features

This study has a Cross-over design.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

Name of ethics committee

Ethical Committee of Isfahan University of Medical Sciences

#### Street address

Isfahan University of Medical Sciences, Hezar Jerib Avenue

#### City

Isfahan

#### Postal code

#### Approval date

2012-12-02, 1391/09/12

#### Ethics committee reference number

391431

## Health conditions studied

### 1

#### Description of health condition studied

diabetes

#### ICD-10 code

E11

#### ICD-10 code description

diabetes mellitus, adult-onset, nonketotic, stable, type II

## Primary outcomes

### 1

#### Description

serum high sensitive-C Reactive Protein (hs-CRP) levels

#### Timepoint

Week 2, Week 8, Week 12, Week 18

#### Method of measurement

high sensitive immunoturbidimetry, mg/dL

### 2

#### Description

serum Inter-Cellular Adhesion Molecule 1 (sICAM-1) levels

#### Timepoint

Week 2, Week 8, Week 12, Week 18

#### Method of measurement

Enzyme-Linked Immunosorbent Assay (ELISA) , $\mu\text{g/L}$

### 3

#### Description

serum vascular cell adhesion molecule 1 (sVCAM-1) levels

#### Timepoint

Week 2, Week 8, Week 12, Week 18

#### Method of measurement

Enzyme-Linked Immunosorbent Assay (ELISA) , $\mu\text{g/L}$

### 4

#### Description

serum high sensitive tumor necrosis factor-alpha (hs TNF- $\alpha$ ) levels

#### Timepoint

Week 2, Week 8, Week 12, Week 18

**Method of measurement**

Enzyme-Linked Immunosorbent Assay (ELISA) .mg/dL

**5****Description**

serum high sensitive Interleukin 6 (hs IL-6) levels

**Timepoint**

Week 2, Week 8, Week 12, Week 18

**Method of measurement**

Enzyme-Linked Immunosorbent Assay (ELISA) .ng/dL

**Secondary outcomes****1****Description**

glycated hemoglobin(HbA1C)

**Timepoint**

Week 2, Week 8, Week 12, Week 18

**Method of measurement**

Ion exchange chromatography

**2****Description**

weight

**Timepoint**

Baseline, Week 2, Week 8, Week 12, Week 18

**Method of measurement**

scale, kilogram

**3****Description**

Waist circumference

**Timepoint**

Baseline, Week 2, Week 8, Week 12, Week 18

**Method of measurement**

meter, centimeter

**4****Description**

body mass index

**Timepoint**

Baseline, Week 2, Week 8, Week 12, Week 18

**Method of measurement**

kg/m<sup>2</sup>, Weight/Height square

**5****Description**

diastolic blood pressure

**Timepoint**

Baseline, Week 2, Week 8, Week 12, Week 18

**Method of measurement**

mmHg, Mercurial sphygmomanometer

**6****Description**

systolic blood pressure

**Timepoint**

Baseline, Week 2, Week 8, Week 12, Week 18

**Method of measurement**

mmHg, Mercurial sphygmomanometer

**7****Description**

fasting blood sugar

**Timepoint**

Week 2, Week 8, Week 12, Week 18

**Method of measurement**

mg/dL, Colorimetric

**8****Description**

serum Triglyceride levels

**Timepoint**

Week 2, Week 8, Week 12, Week 18

**Method of measurement**

photometrics, mg/dL

**9****Description**

serum total cholesterol levels

**Timepoint**

Week 2, Week 8, Week 12, Week 18

**Method of measurement**

photometrics, mg/dL

**10****Description**

serum Low-Density Lipoprotein cholesterol (LDL-c) levels

**Timepoint**

Week 2, Week 8, Week 12, Week 18

**Method of measurement**

Enzymatic, mg/dL

**11****Description**

serum High-Density Lipoprotein cholesterol (HDL-c) levels

**Timepoint**

Week 2, Week 8, Week 12, Week 18

**Method of measurement**

photometrics, mg/dL

**12****Description**

serum insulin levels

**Timepoint**

Week 2, Week 8, Week 12, Week 18

**Method of measurement**

Enzyme-Linked Immunosorbent Assay (ELISA),μU/mL

**13****Description**

HOMA-IR

**Timepoint**

Week 2, Week 8, Week 12, Week 18

**Method of measurement**

Formula

**14****Description**

Body composition

**Timepoint**

Week 2, Week 8, Week 12, Week 18

**Method of measurement**

body analyser

**Intervention groups****1****Description**

soybean flour enriched bread group: soy bread will be enriched by substituting 30% of the wheat flour by soybean flour. participants in the intervention group will be asked to replace 120 gr of soy bread with the equal amount of their usual bread intake.

**Category**

Treatment - Other

**2****Description**

Recommendation group: information about healthy diet has been prescribed for this group. usual dietary recommendation includes healthy food choices. participants in recommendation group will be asked not to consume foods includes soya during this period of study.

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Jomhoori Square, Khorram Street, Endocrine and Metabolism Research Center, Isfahan, Iran

**Full name of responsible person**

Gholamreza Askari

**Street address**

Department of Community Nutrition, School of Nutrition and Food Sciences, Isfahan University of Medical Sciences

**City**

Isfahan

**Sponsors / Funding sources****1****Sponsor**

**Name of organization / entity**

Vice chancellor for research, Isfahan University of Medical Sciences

**Full name of responsible person**

Peyman Adibi

**Street address**

Isfahan University of Medical Sciences, Hezar Jerib Avenue

**City**

Isfahan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Isfahan University of Medical Sciences

**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**

Isfahan University Of Medical Sciences

**Full name of responsible person**

Asma Salarimoghaddam

**Position**

MSc Student Of Nutrition

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

Department Of Clinical Nutrition, School Of Nutrition and Food Sciences, Isfahan University Of Medical Sciences, Hezar Jerib Street, Isfahan

**City**

Isfahan

**Postal code****Phone**

+98 31 1792 2752

**Fax****Email**

salarimoghaddam@hlth.mui.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Isfahan University Of Medical Sciences

**Full name of responsible person**

Asma Salarimoghaddam

**Position**

MSc Student Of Nutrition

**Other areas of specialty/work**

**Street address**

Department Of Clinical Nutrition, School Of Nutrition  
and Food Sciences, Isfahan University Of Medical  
Sciences, Hezar Jerib Street, Isfahan

**City**

Isfahan

**Postal code**

**Phone**

+98 31 1792 2752

**Fax**

**Email**

salarimoghaddam@hlth.mui.ac.ir

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Isfahan University Of Medical Sciences

**Full name of responsible person**

Asma Salarimoghaddam

**Position**

MSc Student Of Nutrition

**Other areas of specialty/work**

**Street address**

Department Of Clinical Nutrition, School Of Nutrition

and Food Sciences, Isfahan University Of Medical  
Sciences, Hezar Jerib Street, Isfahan

**City**

Isfahan

**Postal code**

**Phone**

+98 31 1792 2752

**Fax**

**Email**

salarimoghaddam@hlth.mui.ac.ir

**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*