

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- α) 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

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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- α) 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/m², 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

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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