

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effects of sumac powder capsule (*Rhus coriaria* L.) with restricted calorie diet on anthropometric indices, body composition, level of inflammatory biomarkers, oxidative stress, appetite hormones, glycemic indices, lipid profile and depression in obese or overweight women with depression

Protocol summary

Study aim

Determine the effects of sumac powder with calorie-restricted diet on anthropometric indices, body composition, inflammatory factors, oxidative stress, appetite hormones, glycemic indexes, lipids profile and depression symptoms in overweight or obese women with depression

Design

This study is a randomized double-blind controlled clinical trial with two parallel groups. Sixty-six patients are randomly divided into two groups: sumac and control.

Settings and conduct

Invite overweight or obese individuals referring to nutrition clinic of Shahid Beheshti, After examining the criteria for entering the study, 10cc blood samples are taken. food recall questionnaire, depression, appetite and physical activity questionnaire are completed. Supplements are given to individuals for 6 weeks. For double-blind execution of this research, at the start of the study, the collection of Supplement cans are coded by third person as A and B.

Participants/Inclusion and exclusion criteria

Inclusion: overweight and obesity; moderate and mild depression Exclusion: Use of anti-inflammatory drugs ;antidepressants; Diabetes; inflammatory diseases; Infectious diseases; Acute psychiatric disorders; Sensitivity to sumac

Intervention groups

The intervention group receive a weight loss diet and 3 capsules each contains 1000 mg of sumac and control group receive, weight loss diet and 3 placebo capsules (starch) for 12 weeks.

Main outcome variables

Weight; body massindex; waist circumference; hip circumference; waist to hip; body fat percentage;

visceral fat; fat free mass; serum level of hs-CRP; TNF- α ; IL-6; malondialdehyde; leptin; neuropeptideY; triglyceride; total cholesterol; low density lipoprotein-C; high density lipoprotein-C; glucose; insulin; Insulin resistance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131228015968N6**

Registration date: **2019-05-10, 1398/02/20**

Registration timing: **registered_while_recruiting**

Last update: **2019-05-10, 1398/02/20**

Update count: **0**

Registration date

2019-05-10, 1398/02/20

Registrant information

Name

Atoosa Saidpour

Name of organization / entity

Shahid Beheshti University of Medical Sciences,
School of nutrition

Country

Iran (Islamic Republic of)

Phone

-

Email address

a.saidpour@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-06, 1397/10/16

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of sumac powder capsule (*Rhus coriaria* L.) with restricted calorie diet on anthropometric indices, body composition, level of inflammatory biomarkers, oxidative stress, appetite hormones, glycemic indices, lipid profile and depression in obese or overweight women with depression

Public title

Effects of sumac powder capsule (*Rhus coriaria* L.) with restricted calorie diet on obesity and depression

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Female gender Willingness to cooperate Age 20-65 years Body mass index above 24/9 kg/m² Mild to moderate depression

Exclusion criteria:

Use of anti-inflammation drugs (Steroids and non steroids) Continuous use (more than once a week) of vitamin and mineral supplements with anti-inflammatory and antioxidant properties such as omega-3, vitamin E in the past month Use of weight loss and appetite suppressants Use of antidepressants Diabetes Cases of various autoimmune inflammatory diseases such as multiple sclerosis, rheumatoid arthritis and ... Acute gastrointestinal disease (gastric ulcer, bowel disease, etc.) Chronic kidney or liver disease, with the exception of non-alcoholic fatty liver Infectious diseases up to 1 month before the start of the study Acute mental disorders, Bipolar Disorders, Schizophrenia Weight loss diet in one months ago Surgery in a recent month Sensitivity to sumac Pregnancy Lactation

AgeFrom **20 years** old to **65 years** old**Gender**

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample sizeTarget sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

Individuals are classified into overweight and obese

groups based on body mass index and are randomly assigned to one of the sumac group or placebo group. The random grouping of the two groups is done using Stratified Blocked Randomization. Separate randomization is done within each group. The size of the blocks is 4, with two allocations to the intervention group (A) and two allocations to the placebo group (B). With 6 different permutations, AABB, ABAB, BBAA, BABA, ABBA, BAAB will be created.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double blind clinical trial (patients and researchers). In order to implement this study, at the start of the study, a set of cans contains sumac or placebo are coded by a third party (someone other than the researchers) as A and B.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Institute of Nutrition Research and Food Industry of the country

Street address

No. 7, Hafezi (Arghavan) Ave., Farahzadi Ave., Shahrake Qods(Gharb) town, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1981619573

Approval date

2019-01-01, 1397/10/11

Ethics committee reference number

IR.SBMU.NNFTRI.REC.1397.020

2**Ethics committee****Name of ethics committee**

Ethics committee of Institute of Nutrition Research and Food Industry of the country

Street address

No. 7, Hafezi (Arghavan) Ave., Farahzadi Ave., Shahrake Qods(Gharb) town, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1981619573

Approval date

2019-01-01, 1397/10/11

Ethics committee reference number

IR.SBMU.NNFTRI.REC.1397.019

3

Ethics committee

Name of ethics committee

Ethics committee of Institute of Nutrition Research and Food Industry of the country

Street address

No. 7, Hafezi (Arghavan) Ave., Farahzadi Ave., Shahrake Qods(Gharb) town, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1981619573

Approval date

2019-01-01, 1397/10/11

Ethics committee reference number

IR.SBMU.NNFTRI.REC.1398.001

Health conditions studied

1

Description of health condition studied

Overweight and obesity

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

2

Description of health condition studied

depression

ICD-10 code

F32.0

ICD-10 code description

Major depressive disorder, single episode, mild

Primary outcomes

1

Description

Body weight

Timepoint

before intervention, after 6 weeks of intervention and after 12 weeks of intervention

Method of measurement

seca scale

2

Description

Body Mass Index

Timepoint

Before intervention, after 6 weeks of intervention and after 12 weeks of interventionbefore intervention

Method of measurement

calculation (kg/m2)

3

Description

Waist Circumference

Timepoint

Before intervention, after 6 weeks of intervention and after 12 weeks of interventionbefore intervention

Method of measurement

Meter strip

4

Description

Hip circumference

Timepoint

Before intervention, after 6 weeks of intervention and after 12 weeks of interventionbefore intervention

Method of measurement

Meter strip

5

Description

Waist circumference to hip ratio

Timepoint

Before intervention, after 6 weeks of intervention and after 12 weeks of interventionbefore intervention

Method of measurement

Calculation

6

Description

Body fat percentage

Timepoint

Before intervention, after 6 weeks of intervention and after 12 weeks of interventionbefore intervention

Method of measurement

Body Analyzer

7

Description

Visceral fat

Timepoint

Before intervention, after 6 weeks of intervention and after 12 weeks of interventionbefore intervention

Method of measurement

Body Analyzer

8

Description

Body fat free mass

Timepoint

Before intervention, after 6 weeks of intervention and after 12 weeks of intervention

Method of measurement

Body Analyzer

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

Malondialdehyde

Timepoint

Before intervention and after 12 weeks of intervention

Method of measurement

ELISA

2**Description**

Serum concentration of Leptin

Timepoint

Before intervention and after 12 weeks of intervention

Method of measurement

ELISA

3**Description**

Serum concentration of Neuropeptide Y

Timepoint

Before intervention and after 12 weeks of intervention

Method of measurement

ELISA

4**Description**

Serum concentration of hs-CRP

Timepoint

Before intervention, twelve weeks after intervention

Method of measurement

ELISA

5**Description**

Serum concentration of TNF-alpha

Timepoint

Before intervention, twelve weeks after intervention

Method of measurement

ELISA

6**Description**

Serum concentration of IL-6

Timepoint

Before intervention, twelve weeks after intervention

Method of measurement

ELISA

7**Description**

Serum concentration of glucose

Timepoint

Before intervention, twelve weeks after intervention

Method of measurement

Enzymatic method

8**Description**

Serum concentration of insulin

Timepoint

Before intervention, twelve weeks after intervention

Method of measurement

ELISA

9**Description**

Serum concentration of triglyceride

Timepoint

Before intervention, twelve weeks after intervention

Method of measurement

Enzymatic method

10**Description**

Serum concentration of total cholesterol

Timepoint

Before intervention, twelve weeks after intervention

Method of measurement

Enzymatic method

11**Description**

Serum concentration of High Density Lipoprotein

Timepoint

Before intervention, twelve weeks after intervention

Method of measurement

Enzymatic method

12**Description**

Serum concentration of low density lipoprotein

Timepoint

Before intervention, twelve weeks after intervention

Method of measurement

Enzymatic method

13**Description**

HOMA-IR

Timepoint

calculation ($[\text{Glucose (mg/dl)}] \times [\text{Insulin}]/405$)

Method of measurement

Before intervention, twelve weeks after intervention

14**Description**

Appetite

Timepoint

Before intervention, twelve weeks after intervention
Method of measurement
simple appetite questionnaire

15

Description
Depression
Timepoint
Before intervention, twelve weeks after intervention
Method of measurement
Beck Depression Inventory

Intervention groups

1

Description
Intervention group: daily intake of 3 g sumac powder as 3 capsules of 1000 mg before each meals with weight reduction diet for 12 weeks
Category
Treatment - Drugs

2

Description
Control group: daily intake of 3 g starch as 3 capsules of 1000 mg before each meals with weight reduction diet for 12 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
کلینیک تغذیه و رژیم درمانی دانشگاه علوم پزشکی شهید بهشتی
Full name of responsible person
Nastaran Hariri
Street address
Baran St., Hafezi (Arghavan) Ave., Farahzadi Blvd., Qods (Gharb) twon, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1981619573
Phone
+98 21 2235 7483
Email
nastaranhariri@gmail.com
Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Shahid Beheshti University of Medical sciences- School of Nutrition
Full name of responsible person
Esmat Nasserri
Street address
No. 7, Hafezi (Arghavan) st., Farahzadi Blvd., Qods (Gharb) twon, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1981619573
Phone
+98 21 2235 7483
Email
Nasserri_esm@hotmail.com

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, Shahid Beheshti University of Medical sciences- School of Nutrition
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical sciences- School of Nutrition
Full name of responsible person
Nastaran Hariri
Position
PhD. student of nutrition
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
NO. 7, Hafezi (Arghavan) Ave., Farahzadi Blvd, Qods (Gharb) twon, Tehran
City
Tehran
Province
Tehran
Postal code
1981619573
Phone

+98 21 2235 7483

Email

nastaranhariri@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical sciences-
School of Nutrition

Full name of responsible person

Atoosa Saidpour

Position

PhD of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

No. 7, Hafezi (Arghavan) Ave., Farahzadi Blvd., Qods
(Gharb) twon, tehran, Iran

City

Tehran

Province

Tehran

Postal code

1981619573

Phone

+98 21 2235 7384

Email

atoosa.saidpour@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical sciences-
School of Nutrition

Full name of responsible person

Nastaran Hariri

Position

PhD. student of nutrition

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

NO. 7, Hafezi (Arghavan) Ave., Farahzadi Blvd, Qods
(Gharb) twon, Tehran

City

Tehran

Province

Tehran

Postal code

1981619573

Phone

+98 21 2235 7483

Email

nastaranhariri@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable