Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jul 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
Age
From **20 years** old to **65 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target 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 ([Glucose (mg/dl)]*[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 Nasseri

Street address

No. 7, Hafezi (Arghavan) st., Farahzdi Blvd., Qods (Gharb) twon, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1981619573

Phone

+98 21 2235 7483

Email

Nasseri_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