The effect of Rhus Coriaria (Sumac) supplementation on inflammatory status, insulin resistance and antioxidant status in patients with metabolic syndrome: a randomized, triple-blind crossover clinical intervention

Protocol summary

Study aim
The effect of sumac supplementation on inflammatory status, insulin resistance and antioxidant status in patients with metabolic syndrome: A randomized, triple-blind crossover clinical intervention

Design
A randomized, triple-blind crossover clinical intervention

Settings and conduct
Sedigheh Tahereh Research Center Random allocation method Cross-over triple blind clinical intervention

Participants/Inclusion and exclusion criteria
Inclusion criteria: Agreement to participate in the study, adults aged 20-55 years with metabolic syndrome; Exclusion criteria: illness, taking medication and supplements, pregnancy and lactation, following a special diet

Intervention groups
Intervention group: 20 participants will consume sumac capsules (each capsule: 500 mg, 2 capsules/day) during 4 weeks.; Control group:20 participants will consume Lactose capsules (each capsule: 500 mg, 2 capsules/day) during 4 weeks.

Main outcome variables
Inflammation status, Insulin resistance, Antioxidant status

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: IRCT20200106046022N2
Registration date: 2021-07-22, 1400/04/31
Registration timing: prospective

Last update: 2021-07-22, 1400/04/31
Update count: 0
Registration date
2021-07-22, 1400/04/31

Registrant information
Name
Parvane Saneei
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-23, 1400/05/01
Expected recruitment end date
2021-10-23, 1400/08/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Rhus Coriaria (Sumac) supplementation on inflammatory status, insulin resistance and antioxidant status in patients with metabolic syndrome: A randomized, triple-blind crossover clinical intervention

Public title
Effects of sumac on inflammatory status, insulin
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study Adults 20-55 years old Metabolic syndrome based on modified ATPIII criteria
Exclusion criteria:
Having cardiovascular, liver, kidney, thyroid and diabetes diseases Pregnancy and lactation Follow a special diet Use of drugs that affect appetite, blood pressure, inflammation, fat metabolism and carbohydrates Use of multivitamin-mineral supplements, fatty acids and herbal remedies
Age
From 20 years old to 55 years old
Gender
Both
Phase
2-3
Groups that have been masked
- Participant
- Investigator
- Outcome assessor
- Data analyser
Sample size
Target sample size: 40
Randomization (investigator’s opinion)
Randomized
Randomization description
An unaware person that is not involved in study, will perform block randomization using the website of “WWW.randomization.com” and based on the code assigned to each participants. Such that, subjects will be randomly divided in two groups of intervention and control with a 1:1 allocation ratio. The preparation of sumac and placebo capsules with codes A and B will be determined by a person not involved in sampling and data collection and analysis and researchers don’t know how to distribute it. In each intervention period, group A will be given code A capsules and group B will be given code B capsules.
Blinding (investigator’s opinion)
Triple blinded
Blinding description
In this study, Sumac and Lactosehr II will be replaced in single-color and uniform 500 mg capsules. Participants, researchers and statisticians will not be aware of the type of capsules
Placebo
Used
Assignment
Crossover
Other design features
Secondary Ids
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezar Jerib Ave
City
Isfahan
Province
Isfahan
Postal code
8174673461
Approval date
2021-05-29, 1400/03/08
Ethics committee reference number
IR.MUI.RESEARCH.REC.1400.076

Health conditions studied

1
Description of health condition studied
metabolic syndrome
ICD-10 code
E88.81
ICD-10 code description
Metabolic syndrome

Primary outcomes

1
Description
Insulin resistance (Fasting blood sugar, Insulin, HOMA-IR, QUICKI)
Timepoint
At the beginning and end of each Six-week intervention
Method of measurement
Existing commercial kits

2
Description
Antioxidant status (MDA,CTL,SOD)
Timepoint
At the beginning and end of each Six-week intervention
Method of measurement
Existing commercial kits

3
Description
Inflammation status (CRP)
Timepoint
At the beginning and end of each Six-week intervention
Method of measurement
Existing commercial kits
Secondary outcomes

1
Description
Waist Circumference
Timepoint
At the beginning and end of each intervention period
Method of measurement
Meters irreversible

2
Description
Weight
Timepoint
At the beginning and end of each intervention period
Method of measurement
Digital Balance

3
Description
BMI
Timepoint
At the beginning and end of each intervention period
Method of measurement
Divide the weight by the square of the height

Intervention groups

1
Description
Intervention group: 500 mg capsules of sumac daily, two with food for 6 weeks in the first period of the intervention. In the second period of the intervention of this group, they are in the control group. The capsules are filled with sumac powder powdered by the researcher due to the reduction of counterfeits.
Category
Treatment - Drugs

2
Description
Control group: Lactose 500 mg capsules daily with food for 6 weeks in the first period of the intervention. In the second period of the intervention, this group is in the intervention group. The capsules are filled by the researcher with lactose.
Category
Placebo

Recruitment centers

1
Recruitment center
Name of recruitment center
Sedigheh Tahereh Research Center
Full name of responsible person
Saneei Parvane
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Sponsors / Funding sources

1
Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
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
Esfahan University of Medical Sciences
Full name of responsible person
Parvane Saneei
Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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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
No - There is not a plan to make this available

Data Dictionary
Not applicable