Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Assessment the effect of green tea and wheat bran on diagnostic indicators of metabolic syndrome in Shahroud drivers in 2020

Protocol summary

Study aim

Determining the effect of green tea and wheat bran on the diagnostic indicators of Metabolic Syndrome on Shahroud drivers in 2020

Design

A clinical trial with two intervention groups and one control group, with permuted blocks randomization, without blinding

Settings and conduct

After obtaining the Ethic Code and Registration at the Iranian Clinical Trial Center, investigating the drivers with health record in Kasra occupational clinic will be started. Then 90 patients with metabolic syndrome based on ATP (Adult Treatment Panel) definition will include to the study. After that, they will divide into the 2 intervention groups and 1 control group by permuted blocks randomization. Before the interventions, parametric and laboratory variables will assessed and then after 2 months will reassess.

Participants/Inclusion and exclusion criteria

Inclusion criteria: consent for study participation, existence of driver's health record, metabolic syndrome based on ATP (Adult Treatment Panel) definition, age range 40-50 years Exclusion criteria: history of a gastrointestinal disease and/or a liver disease, treatment with corticosteroid medications (causes overweight due to peripheral edema).

Intervention groups

Participants will be divided into 3 groups (green tea, bran and control) with 30 individuals for each group for 2 months. The green tea group will consume 3 cups of green tea bag (one gram) daily without added sugar or milk and the bran group will consume 3.5 gram wheat bran powder daily in combination with yogurt or rice. Products with sanitary packaging and standard logos will be offered to intervention groups. The control group will consume 3 cups of water daily.

Main outcome variables

Laboratory tests (High Density Lipoprotein, Fasting Blood Sugar,Triglyceride), measuring blood pressure and waist circumference.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200217046524N1**
Registration date: **2020-05-25, 1399/03/05**
Registration timing: **retrospective**

Last update: **2020-05-25, 1399/03/05**
Update count: **0**

Registration date

2020-05-25, 1399/03/05

Registrant information

Name

Mina Shayestefar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3345 0193

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2020-04-19, 1399/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Assessment the effect of green tea and wheat bran on diagnostic indicators of metabolic syndrome in Shahroud drivers in 2020

Public title
Assessment the effect of green tea and wheat bran on metabolic syndrome

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Satisfaction to participate in the study Existence driver's health record Metabolic syndrome based on ATP definition Age range 40 to 50 years

Exclusion criteria:
A history of gastrointestinal disease A history of liver disease Being treated with corticosteroid drugs

Age
From **40 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation will be done using six Permuted Block Randomization methods. The total number of participants in this study is 90, which will be included in 3 groups of 30 people (2 intervention groups and one control group). 10 blocks of 6 will be determined and we will give each block from one to 10 numbers. Then, using the table of random numbers, 15 one-digit numbers (between 0 and 9) are selected completely randomly, and based on each of the selected numbers, a block is determined from the ten blocks (each of the randomly numbers will be corresponding to the same block number except for the number zero which corresponds to the tenth block). Eligible individuals are assigned to three groups based on the arrangement of each block from left to right.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Semnan University of Medical Sciences

Street address
Semnan University of Medical Sciences, Basij Avenue

City
Semnan

Province
Semnan

Postal code
3514799442

Approval date
2020-02-04, 1398/11/15

Ethics committee reference number
IR.SEMUMS.REC.1398.274

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
Height

Timepoint
The measurement will be performed at baseline and before the intervention.

Method of measurement
By the meter

2

Description
Weight

Timepoint
Measurements will be taken at the beginning of the study before the intervention and will be repeated after 2 months and at the end of the intervention.

Method of measurement
By a balance scales

3

Description
Systolic & Diastolic pressure

Timepoint
Measurements will be taken at the beginning of the study before the intervention and will be repeated after 2

months and at the end of the intervention.

Method of measurement

By a Sphygmomanometer

4

Description

Abdominal circumference

Timepoint

Measurements will be taken at the beginning of the study before the intervention and will be repeated after 2 months and at the end of the intervention.

Method of measurement

By a meter

5

Description

Fasting Blood Sugar

Timepoint

Measurements will be taken at the beginning of the study before the intervention and will be repeated after 2 months and at the end of the intervention.

Method of measurement

By a Micro-plate Eliza Reader with Parsazmun kits

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Description

Triglycerides

Timepoint

Measurements will be taken at the beginning of the study before the intervention and will be repeated after 2 months and at the end of the intervention.

Method of measurement

By a Micro-plate Eliza Reader with Parsazmun kits

7

Description

High Density Lipoprotein

Timepoint

Measurements will be taken at the beginning of the study before the intervention and will be repeated after 2 months and at the end of the intervention.

Method of measurement

By a Micro-plate Eliza Reader with Parsazmun kits

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: Green Tea- To the Green Tea Group will be recommended 3 cups of simple green teabag (one gram) daily from without added sugar or milk for 2 months. There will be provided from hygienic packaging products from Golestan brand with standard logo.

Category

Treatment - Other

2

Description

Second intervention group: Wheat bran- To the wheat bran group will be recommended 3.5 gram wheat bran powder based on individual taste with yogurt or rice daily for 2 months. There will be provided from hygienic packaging products of Nan Avaran brand with standard logo.

Category

Treatment - Other

3

Description

Control group: For the control group, 3 cups of water per day more than last daily consumption will be recommended.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Kasra occupational medicine center

Full name of responsible person

Mina Shayestefar

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No 2, first floor, first block, Pasargad building, Negarestan street, Baghzendan Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Parviz Kokhaei

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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
Semnan 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
Semnan University of Medical Sciences
Full name of responsible person
Mina Shayestefar
Position
Instructor, faculty member
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary

Not applicable

Title and more details about the data/document

All data, protocols and forms of conscious consent can be shared (after individuals have been unrecognizable), .

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

It will only be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

No analysis should be performed on the data.

From where data/document is obtainable

Email: m.shayestefar@semums.ac.ir Mina Shayestehfar - Faculty Member of Semnan University of Medical Sciences

What processes are involved for a request to access data/document

After reviewing the application and 6 months have passed since the results were published, the data will be sent within a week if the application of results are confirmed for the applicant.

Comments