

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The effect of Moringa oral product on inflammatory factors, insulin resistance and abdominal obesity in military with metabolic syndrome, clinical trial

Protocol summary

Study aim

General objective: To determine the effect of Moringa oral product consumption on inflammatory factors and insulin resistance and abdominal obesity in soldiers with metabolic syndrome. Application goal: using the results of this plan to improve disease and inflammation in soldiers suffering from metabolic syndrome

Design

A controlled, double-blind, randomized, phase 3 clinical trial on 102 patients. Blocks of 4 are used for randomization.

Settings and conduct

In order to carry out this research in a double-blind manner, before starting the study, the cans containing the respective pills are coded as A and B by someone other than the researcher, so that the researcher does not know the type of pill received by each group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Completing the consent form and interest in participating in the study; Waist circumference higher than 80 cm in women and higher than 94 cm in men (main IDF criteria); Having criteria for metabolic syndrome (according to the International Diabetes Federation) Non-entry criteria: Unwillingness to continue studying at any stage of project implementation; Trying to get pregnant; Diagnosing of the disease or starting drug treatment; Incidence of intolerance to moringa food products.

Intervention groups

Determining the dose of the drug based on the extraction of moringa extract will be determined in the process of doing the work (2 grams) and the duration of the intervention will be 8 weeks based on the available evidence. Control group (placebo): a syrup that is similar in color and smell to the syrup of the intervention group, but does not contain the main drug, for 8 weeks.

Main outcome variables

Hs-CRP; ESR; TNF- α ; IL-6; MDA; Glycosylated hemoglobin; insulin; HOMA-IR; Abdominal fat percentage; Weight; BMI; Waist circumference

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230720058857N1**

Registration date: **2023-07-31, 1402/05/09**

Registration timing: **prospective**

Last update: **2023-07-31, 1402/05/09**

Update count: **0**

Registration date

2023-07-31, 1402/05/09

Registrant information

Name

Mohammad Rashidmayvan

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-21, 1402/05/30

Expected recruitment end date

2024-03-18, 1402/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Moringa oral product on inflammatory factors, insulin resistance and abdominal obesity in military with metabolic syndrome, clinical trial

Public title

Effect of Moringa in metabolic syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 20-60 years old - no specific underlying disease (such as malignancy, kidney and liver failure) - no pregnancy or breastfeeding - no allergy to moringa food product - no smoking and alcohol consumption - Completion of the consent form and interest in participating in the study - Waist circumference above 80 cm in women and above 94 cm in men (the main criterion of IDF) - Having the criteria of metabolic syndrome (according to the International Diabetes Federation)

Exclusion criteria:**Age**

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

The type of randomization will be block type. Classification of people based on the age of 18 to 40 and 40 to 60 years, gender (male/female) and BMI (25 to 30 and 30 to 40) has been done using blocks of four (In order to distribute confounders equally in two groups at each time point of the study). Identification codes of patients in the randomized list will be obtained through the site related to random blocks.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to carry out this research in a double-blind manner, before starting the study, the cans containing the respective pills are coded as A and B by someone other than the researcher, so that the researcher does not know the type of pill received by each group. In addition, the patient himself does not know about the contents of the syrup.

Placebo

Used

Assignment

Factorial

Other design features**Secondary Ids**

empty

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

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Province

Tehran

Postal code

021-86096350-5

Approval date

2023-06-18, 1402/03/28

Ethics committee reference number

IR.AJAUMS.REC.1402.058

Health conditions studied**1****Description of health condition studied**

Metabolic syndrome

ICD-10 code

66

ICD-10 code description

E-66

Primary outcomes**1****Description**

Tumor necrosis factor-alpha

Timepoint

At the beginning of the study and 8 weeks after starting the Moringa supplement

Method of measurement

Blood sample

2**Description**

High sensitive C reactive protein

Timepoint

At the beginning of the study and 8 weeks after starting the Moringa supplement

Method of measurement

Blood sample

3

Description

Erythrocyte sedimentation rate

Timepoint

At the beginning of the study and 8 weeks after starting the Moringa supplement

Method of measurement

Blood sample

4

Description

Interleukin 6

Timepoint

At the beginning of the study and 8 weeks after starting the Moringa supplement

Method of measurement

Blood sample

5

Description

Malondialdehyde

Timepoint

At the beginning of the study and 8 weeks after starting the Moringa supplement

Method of measurement

Blood sample

6

Description

Insulin

Timepoint

At the beginning of the study and 8 weeks after starting the Moringa supplement

Method of measurement

Blood sample

7

Description

Glycated Hemoglobin

Timepoint

At the beginning of the study and 8 weeks after starting the Moringa supplement

Method of measurement

Blood sample

8

Description

Homeostatic Model Assessment for Insulin Resistance

Timepoint

At the beginning of the study and 8 weeks after starting the Moringa supplement

Method of measurement

Blood sample

9

Description

Body fat percentage

Timepoint

At the beginning of the study and 8 weeks after starting the Moringa supplement

Method of measurement

Body analyzer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Military patients with metabolic syndrome taking 2 grams of Moringa supplement daily for 8 weeks.

Category

Prevention

2

Description

Control group: Military patients with metabolic syndrome taking 2 grams of placebo daily for 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

بیمارستان 550 ارتش

Full name of responsible person

Mohammad rashidmayvan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Vahid Hadi

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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
Artesh 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
Gonabad University of Medical Sciences

Full name of responsible person
Mohammad Rashidmayvan

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
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Person responsible for updating data

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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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The protocol article will be published after obtaining the clinical trial code and the intervention article after the completion of the study.

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

Supervisors and adviser

Under which criteria data/document could be used

In order to request journals for the validity of the study and to follow up the study

From where data/document is obtainable

Mohammad Rashidmayvan Vahid Hadi

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

After the official request in writing or by email, it will be sent within 2 weeks.

Comments