

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Designing and evaluation of food ration formulation aimed to promote health in crisis situations

#### Protocol summary

##### Study aim

Designing a pragmatic operational diet with specific features that will improve performance and provide adequate energy and reduce fatigue and stress in military personnel in combat operations.

##### Design

Phase I) Formulation Design Phase II) Safety and Quality Phase III) Clinical trial: A pilot study and clinical trial will be conducted. Individuals with age range of 18 to 50 years old will be included in the study, randomly divided into 2 groups of 17 people: the first group received the intervention, receiving ration with the pragmatic compounds, and the second groups of the control group receiving traditional used rations with the same calorie content. Food rations will be distributed to target groups within a 10 day training period. Before and after the intervention, physical fitness indexes, serum levels of Hsp72, total antioxidant capacity, oxidant index, inflammatory factor, blood lactate, venous blood gases, appetite and physical activity measurements through a pedometer will be recorded.

##### Settings and conduct

Food rations will be distributed to target populations during an operational military training course for target groups over a 10-day operation. Diets will be consumed in the form of compressed food in three meals, each with a weight of 140 grams and 700 kilocalories of energy per serving.

##### Participants/Inclusion and exclusion criteria

Army military personnel are in the camp during a hard military training period.

##### Intervention groups

Group 1: intervention group, Receive Compact Food ration with pragmatic and beneficial compounds Group 2: control group, traditional rations used in operational areas with the same amount of calories.

##### Main outcome variables

Evaluation of functional and fatigue indices by physical fitness and exams

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20121216011763N43**

Registration date: **2020-01-13, 1398/10/23**

Registration timing: **prospective**

Last update: **2020-01-13, 1398/10/23**

Update count: **0**

##### Registration date

2020-01-13, 1398/10/23

##### Registrant information

##### Name

Gholamreza Askari

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 1792 2110

##### Email address

askari@mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-03-20, 1399/01/01

##### Expected recruitment end date

2020-04-08, 1399/01/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Designing and evaluation of food ration formulation aimed to promote health in crisis situations

## Public title

The effect of food ration on health promotion

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

Military personnel are maneuvering operations Age range 18-50 years Do not use antioxidant and herbal supplements at least 1 month before starting the study Willingness to cooperate and sign a conscientious consent form after full knowledge of the goals and method of the study

### Exclusion criteria:

Special Diet for at least 6 months History of any allergies and allergies to certain compounds smoking Use of any antioxidant and anti-inflammatory nutritional supplement during the study Unwillingness to participate in the study or continue cooperation

## Age

From **18 years** old to **50 years** old

## Gender

Male

## Phase

N/A

## Groups that have been masked

- Participant
- Data analyser

## Sample size

Target sample size: **34**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Samples were randomly selected using randomized block method and RAS software was divided into 3 groups of 15, the first group received intervention, receiving diet with functional and extractive compounds, and the second and third groups of control, respectively, receiving the ration of pragmatic and usual diet Used in operational areas with the same amount of calories.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Stratified block randomization

## Placebo

Not used

## Assignment

Parallel

## 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

Vice Chancellor for Research, Esfahan University of Medical Sciences, Hezarjerib Street

#### City

Esfahan

#### Province

Isfahan

#### Postal code

73461846

#### Approval date

2019-11-24, 1398/09/03

#### Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.473

## Health conditions studied

## 1

### Description of health condition studied

healthy people

### ICD-10 code

### ICD-10 code description

## Primary outcomes

## 1

### Description

Total antioxidant capacity

### Timepoint

At baseline and after 10 day of intervention

### Method of measurement

blood sample

## 2

### Description

Malondialdehyde

### Timepoint

At baseline and after 10 day of intervention

### Method of measurement

Spectrophotometry

## 3

### Description

High-sensitivity C-reactive protein

### Timepoint

At baseline and after 10 day of intervention

### Method of measurement

Immunoturbidimetry

## Secondary outcomes

## 1

### Description

maximum rate of oxygen consumption (vo2max)

### Timepoint

At baseline and after 10 day of intervention

### Method of measurement

step test

## Intervention groups

## 1

### Description

Intervention group: Receive Compact Food ration with pragmatic and beneficial compounds for 10 days

### Category

Other

## 2

### Description

Control group: Receive Compact Food ration without pragmatic and beneficial compounds for 10 days

### Category

Other

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Army of the Islamic Republic of Iran

#### Full name of responsible person

Saeid Hadi

#### Street address

Army University of Medical Sciences, West Fatemi Street, Tehran

#### City

Tehran

#### Province

Tehran

#### Postal code

9137913316

#### Phone

+98 21 4382 2284

#### Email

s.hadinu@yahoo.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Esfahan University of Medical Sciences

#### Full name of responsible person

Dr. Shaghayegh Haghjoo

#### Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Hezarjereb Street

### City

Esfahan

### Province

Isfahan

### Postal code

73461846

### Phone

+98 31 3668 8138

### Email

Sh\_Haghjoo@med.mui.ac.ir

### 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

Dr. Gholamreza Askari

#### Position

Professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Nutrition

#### Street address

Faculty of Medicine, Esfahan University of Medical Sciences, Paradise Daneshgah, Azadi Square

#### City

Esfahan

#### Province

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#### Postal code

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#### Phone

+98 31 3792 3171

#### Email

askari@mui.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Esfahan University of Medical Sciences

**Full name of responsible person**

Dr. Gholamreza Askari

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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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**

Yes - There is 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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

The non-identifiable individual participant data collected in this study will be shared. Also, The protocol, results, and statistical analysis of the current study will be published in the relevant articles.

**When the data will become available and for how long**

The non-identifiable individual participant data will become available after the publication of the relevant articles.

**To whom data/document is available**

The non-identifiable individual participant data will become available to other researchers in academic institutions.

**Under which criteria data/document could be used**

The non-identifiable individual participant data can only be used for research.

**From where data/document is obtainable**

The non-identifiable individual participant data will be obtainable by sending an e-mail to Dr. Gholamreza askari. ( askari@mui.ac.ir)

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

Other researchers in academic institutions can send their request to Dr. Gholamreza askari.

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Saeid Hadi

**Position**

PhD student

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

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