

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Design and evaluation of humanitarian ration formulations in crisis with emphasis on functional capacity and oxidative stress levels.

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 3 groups of 15 people: the first group received the intervention, receiving ration with the pragmatic compounds, and the second and third groups of the control group receiving respectively ration without of pragmatic compounds and 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, Receive Compact Food ration without pragmatic compounds Group 3: 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: **IRCT20181014041336N1**

Registration date: **2019-01-15, 1397/10/25**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-15, 1397/10/25**

Update count: **0**

Registration date

2019-01-15, 1397/10/25

Registrant information

Name

Vahid hadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3800 2417

Email address

hadiv941@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-21, 1397/09/30

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Design and evaluation of humanitarian ration formulations in crisis with emphasis on functional capacity and oxidative stress levels.

Public title
The effect of pragmatic rations on the performance of military personnel with intense activity

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
- Investigator
- Data analyser

Sample size
Target sample size: **45**

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
Used

Assignment
Parallel

Other design features
Our goal is to formulate a diet with military application, treatment and use in crisis and review it in the form of a

clinical trial.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

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Razavi Khorasan

Postal code

9177948564

Approval date

2018-10-24, 1397/08/02

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.276

Health conditions studied

1

Description of health condition studied

Military personnel in operational maneuvers

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

3**Description**

Control group: traditional rations used in operational areas 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

Vahid Hadi

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Army University of Medical Sciences- Shahid Etemadzadeh -West Fatemi St.-Tehran

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

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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

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Abdolreza Norouzi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Vahid Hadi

Position

Ph.D. student

Latest degree

Master

Other areas of specialty/work

Nutrition

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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. Abdul Reza norouzy. (Norouzya@mums.ac.ir)

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

Other researchers in academic institutions can send their request to Dr. Abdul Reza Norouzy.

Comments