Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 1) 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

City

Mashhad

Province

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
Street address
Army University of Medical Sciences- Shahid Etemadzadeh -West Fatemi St.-Tehran
City
Tehran
Province
Tehran
Postal code
9137913316
Phone
+98 21 4382 2284
Email
vahidhadi1@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafaghodi
Street address
Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
91775-1365
Phone
+98 51 1882 3255
Fax
+98 51 1882 3251
Email
tafaghodim@mums.ac.ir
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
Street address
Faculty of Medicine, Mashhad University of Medical

Sciences, Paradise Daneshgah, Azadi Square
City
Mashhad
Province
Razavi Khorasan
Postal code
91779-48564
Phone
+98 51 3882 7033
Fax
+98 51 3800 2421
Email
Norouzya@mums.ac.ir

Person responsible for scientific 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
Street address
Faculty of Medicine, Mashhad University of Medical Sciences, Paradise Daneshgah, Azadi Square
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Phone
+98 51 3882 7033
Fax
+98 51 3800 2421
Email
Norouzya@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Vahid Hadi
Position
Ph.D. student
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
Faculty of Medicine, Mashhad University of Medical Sciences, Paradise Daneshgah, Azadi Square
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Phone
+98 51 3882 7033
Email
Hadiv941@mums.ac.ir

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