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 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 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

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Gholamreza Askari

Name of organization / entity
Isfahan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-20, 1399/01/01

Expected recruitment end date
2020-04-08, 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
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Province
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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
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Saeid Hadi
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Sponsors / Funding sources

1

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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
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
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Full name of responsible person
Dr. Gholamreza Askari
Position
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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