Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluating the Effect of Yogurt Fortified with beta-Hydroxy beta-Methyl Butyrate (HMB), Vitamin D, and Vitamin C on Fat-Free Mass, Muscle Strength, and Physical Functionality in Sarcopenic Elderly

Protocol summary

Study aim

The aim of current study is evaluation of the efficacy of 12-week yogurt fortified with beta-Hydroxy beta-Methyl Butyrate (HMB), vitamin D, and C on fat-free mass, muscle strength, and physical performance in older adults with sarcopenia.

Design

In this research, a total of 60 eligible sarcopenic elderly people participate in a 12-week randomized, double-blind, placebo-controlled clinical trial. The active group (n=30) receive a yogurt fortified with HMB, vitamin D and C to consume daily for 12 weeks. The control group (n=30) receive iso-caloric control yogurt to consume daily for 12 weeks. In this study, we examine body composition with dual-energy X-ray absorptiometry (DXA) and Bioelectrical Impedance Analysis (BIA), muscle strength with handgrip dynamometer, and blood biochemical indexes of nutritional and health status, and evaluate nutritional status, physical function, and quality of life before and after the 12-week intervention.

Settings and conduct

Recruitment and initial assessment will be carried out in the 6 medical centers at Shiraz city. Sarcopenia assessment will be performed in Hormone Laboratory and Bone Densitometry Department, Namazi Hospital.

Participants/Inclusion and exclusion criteria

Participants are eligible to participate if they are diagnosed with sarcopenia according to EWGSOP guidelines. Subjects are not invited if they have comorbidities such as kidney or liver failure, malignancies, Congestive Heart Failure (CHF), Chronic Obstructive Pulmonary Disorder (COPD), or/and are using medications interfering with nutritional intervention such as steroids, heparin, free amino acid, antioxidant, omega-3, vitamin D supplements. Participant are excluded if they are unwillingness to continue the study.

Intervention groups

Participants in case group consume daily 400 grams pre-packaged yogurt fortified with HMB, Vitamin D, and C and control group consume 400 grams per day pre-packaged placebo yogurt that have no additional ingredients.

Main outcome variables

Skeletal Muscle mass Index (SMI); Hand Grip Strength (HGS), Physical performance; anthropometric indices; biochemical parameters; nutritional status; physical activity and quality of Life.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171223038017N1**
Registration date: **2018-01-09, 1396/10/19**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-09, 1396/10/19**
Update count: **0**

Registration date

2018-01-09, 1396/10/19

Registrant information

Name

Nasrin Nasimi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2017-08-06, 1396/05/15
Expected recruitment end date
2018-02-04, 1396/11/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the Effect of Yogurt Fortified with beta-Hydroxy beta-Methyl Butyrate (HMB), Vitamin D, and Vitamin C on Fat-Free Mass, Muscle Strength, and Physical Functionality in Sarcopenic Elderly

Public title
Effect of Yogurt Fortified with beta-Hydroxy beta-Methyl Butyrate (HMB) in Sarcopenic Elderly
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Men and women aged 65 years and older Sarcopenia diagnosis according to European Working Group on Sarcopenia in Older People (EWGSOP) guidelines
Exclusion criteria:
Subjects unable to move without crutches, walker or other assistive devices. Subjects with artificial limbs. Subjects with history of chronic disease (e.g. Congestive Heart Failure (CHF), Chronic Obstructive Pulmonary Disorder (COPD), Chronic Renal Failure (CRF), cirrhosis liver failure and active cancer). Subjects with history of kidney stones. Subjects who regularly consume any medications interfering with nutritional intervention (e.g. steroids, heparin, free amino acid, antioxidant, omega-3, vitamin D supplements).
Age
From **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Individuals will be classified into placebo and target groups with block randomization and Random allocation methods.
Blinding (investigator's opinion)
Double blinded
Blinding description
All participants in this study are unaware about their grouping because the package, label, and appearance of the target and placebo yogurt are quite similar. Since participants are not referred based on their group to clinical follow-up and outcome evaluator and he/she is also unaware of the separation of individuals. The principle investigators are not directly connected with the participants, so they are not aware of their grouping. An importer of data will also be outside the study system, which is generally unaware of the nature of the study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences
Street address
Shiraz University of Medical Sciences, Zand street
City
Shiraz
Province
Fars
Postal code
7134814336
Approval date
2017-07-30, 1396/05/08
Ethics committee reference number
IR.SUMS.REC.1396.89

Health conditions studied

1

Description of health condition studied
Sarcopenia
ICD-10 code
M62.84
ICD-10 code description
Sarcopenia

Primary outcomes

1

Description
Fat-free mass
Timepoint
Before and after intervention
Method of measurement

Dual energy X-ray Absorptiometry (DXA); Bioelectrical Impedance Analysis (BIA)

Secondary outcomes

1

Description
Hand grip
Timepoint
Before and after intervention
Method of measurement
Hydraulic Hand Dynamometer

2

Description
Physical performance (gait speed)
Timepoint
Before and after intervention
Method of measurement
Stopwatch

3

Description
Physical activity
Timepoint
Before and after intervention
Method of measurement
International Physical Activity Questionnaire (IPAQ)

4

Description
Nutritional status
Timepoint
Before and after intervention
Method of measurement
Mini Nutritional Assessment (MNA) questionnaire

5

Description
Quality of life
Timepoint
Before and after intervention
Method of measurement
The Short Form Health Survey-12 (SF-12) questionnaire

6

Description
25- hydroxy vitamin D (25-OHD) level
Timepoint
Before and after intervention
Method of measurement
Chemiluminescence immunoassay (CLIA) method

7

Description
Albumin level
Timepoint
Before and after intervention
Method of measurement
Enzyme-linked immunosorbent assay (ELISA) kit

8

Description
Creatinine level
Timepoint
Before and after intervention
Method of measurement
Jaffe’s method

9

Description
C-Reactive Protein (hs-CRP) level
Timepoint
Before and after intervention
Method of measurement
Enzyme-linked immunosorbent assay (ELISA) kit

10

Description
Insulin-like Growth Factor – 1 (IGF-1)
Timepoint
Before and after intervention
Method of measurement
Chemiluminescence immunoassay (CLIA) method

11

Description
Fasting Blood Sugar (FBS) level
Timepoint
Before and after intervention
Method of measurement
Auto analyser

12

Description
Fasting insulin level
Timepoint
Before and after intervention
Method of measurement
Enzyme-linked immunosorbent assay (ELISA) kit

13

Description
Malondialdehyde (MDA) level
Timepoint
Before and after intervention
Method of measurement
Spectrophotometry

14

Description
Blood urea nitrogen level
Timepoint

Before and after intervention

Method of measurement

Chemical Method (Diazine)

15

Description

Lipid profile (LDL, HDL, Triglyceride, total Cholesterol)

Timepoint

Before and after intervention

Method of measurement

Chemical Method (Kit)

Intervention groups

1

Description

Intervention group: receiving 400 grams per day of yogurt fortified with beta-hydroxy beta-butyl butyrate (HMB), vitamin D, and C for 12-week intervention that were produced by Zarrin Ghazal Industrial Co. (Daity)

Category

Rehabilitation

2

Description

Control group: receiving 400 grams per day of placebo yogurt for 12-week intervention that were produced by Zarrin Ghazal Industrial Co. (Daity)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hassan Comprehensive Health Center

Full name of responsible person

Dr. Majid Esmailzadeh

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South Fajr Ave., Valfajr Town., Amirkabir Blvd.

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2

Recruitment center

Name of recruitment center

Fatemeh Al-zahra Comprehensive Health Center

Full name of responsible person

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3

Recruitment center

Name of recruitment center

Imam Reza Comprehensive Health Center

Full name of responsible person

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4

Recruitment center

Name of recruitment center

Razii Health Center

Full name of responsible person

Ali Zare

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5

Recruitment center

Name of recruitment center

Mohammad Rasolallah Health center

Full name of responsible person

Maryam Hadadiyan

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6

Recruitment center

Name of recruitment center
Eghbal Health Center

Full name of responsible person
Dr. Ali Mohammad Kavosh

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7

Recruitment center

Name of recruitment center
Rezvan Health Center

Full name of responsible person
Dr. Asghar Tavakol

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next to Elahie Shopping Center., Shahid Motahari Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Dr. Seyed Basir Hashemi

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Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shiraz University of Medical Sciences

Proportion provided by this source
80

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

2

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr. Mohammad Hossein Dabbaghmanesh

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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
Shiraz University of Medical Sciences

Proportion provided by this source
20
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
Shiraz University of Medical Sciences
Full name of responsible person
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Position
Professor
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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable