

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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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stud2281109658@sums.ac.ir

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).

AgeFrom **65 years** old**Gender**

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample sizeTarget 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
Street address
South Fajr Ave., Valfajr Town., Amirkabir Blvd.
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enghelab@sums.ac.ir

2

Recruitment center
Name of recruitment center
Fatemeh Al-zahra Comprehensive Health Center
Full name of responsible person

Dr. Reza Mohammadi
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3

Recruitment center
Name of recruitment center
Imam Reza Comprehensive Health Center
Full name of responsible person
Dr. Leyla Bagheri
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next to AL-ahmad School, Koshan Ave.
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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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Passargad Square, Passargad Blvd

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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

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Seyed Basir Hashemi

Street address

Office of Research and Technology, Seventh Floor,
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Sciences, Zand Street

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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

Street address

Office of Vice chancellor for research (Endocrine and
Metabolic), Central Building of Shiraz University of
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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

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

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hossein Dabbaghmanesh

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Endocrine and Metabolic

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Contact**Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Nasrin Nasimi

Position

MSc student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Sharing plan**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Zahra Sohrabi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Department of Nutrition and Food Science, Fatholmobin alley, Razi blvd

City**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