

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Evaluation of the efficacy of high protein high calorie diet include L-Arginine, L-Glutamine and β -Hydroxy β -Methylbutyrate on pressure ulcers and anthropometric indices in 20-50 years adults

Protocol summary

Study aim

Evaluation of the effectiveness of high-calorie high-protein diet containing L-glutamine, L-arginine and beta hydroxybeta-methyl butyrate on the improvement of compression wounds and anthropometric indicators in people aged 20-20 years in Kermanshah

Design

This study was conducted in a clinical trial with a blinded double-blind, 42 patient 20-50 years with bedsores who will be randomly assigned to the control and intervention groups.

Settings and conduct

This study will be performed on 42 patients aged 20-50 with bed sores in Imam Reza Hospital in Kermanshah for 2 weeks. After explaining the objectives of the research and obtaining conscious consent, the subjects were evaluated for compressive wound condition and anthropometric indicators. Will take. Patients' wound status will be assessed using the Pressure Ulcer Scale for Healing (PUSH) index, and then individuals will be classified into control and intervention groups.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age 50-20 years and willingness to cooperate in the project by the individual or a family member, not to be under special diets in the last 6 months, not to be infected with endocrine, liver, kidney, thyroid, lack of disease Taking steroid or hormonal medications. Exclusion criteria: undergoing surgery in the last 2 weeks

Intervention groups

Intervention group: on a high-protein-high-calorie diet with two sachets per day (noon and evening) of dietary supplements containing L-glutamine, L-arginine and beta-hydroxybeta-methyl butyrate (each 26-gram sachet containing 7.3 g of carbohydrates, 7 Grams of L-arginine, 7 grams of L-glutamine and 1.5 grams of calcium beta-hydroxybeta-methyl butyrate) and control group: will be

on a high-protein-high-calorie diet with placebo consumption.

Main outcome variables

The degree of bed sore

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181111041611N4**

Registration date: **2020-07-09, 1399/04/19**

Registration timing: **prospective**

Last update: **2020-07-09, 1399/04/19**

Update count: **0**

Registration date

2020-07-09, 1399/04/19

Registrant information

Name

Mehnoosh Samadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3710 2009

Email address

mehnoosh_samadi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the efficacy of high protein high calorie diet include L-Arginine, L-Glutamine and β -Hydroxy β -Methylbutyrate on pressure ulcers and anthropometric indices in 20-50 years adults

Public title
Evaluation of the efficacy of high protein high calorie diet include L-Arginine, L-Glutamine and β -Hydroxy β -Methylbutyrate on pressure ulcers and anthropometric indices in 20-50 years adults in Kermanshah.

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Not being on special diets for the past 6 months Lack of endocrine, hepatic, renal and thyroid disease Do not take steroid or hormonal medications
Exclusion criteria:
Not having surgery in the last 2 weeks

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: Simple randomization
Randomization tool: sealed envelope In this way, by attending the hospital, patients with the criteria for entering the study will be selected and 42 of them will be selected for the intervention and control groups in sealed envelope method. In this way, we first call the intervention group "a" and the control group "b". Then we write the names of the patients in separate envelopes and number them; in the next step, the envelopes with the even numbers will receive the intervention "a" and the envelopes with the odd numbers will receive the intervention "b" or vice versa. It should be noted that we will not know the names inside the envelope when counting the envelopes.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the researchers and participants will not be aware of the allocation of groups, and the supplements appearance will be similar in both groups. The supplemented manufacturer will encoded the

supplements before delivery.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Kermanshah University of Medical Sciences Ethics Committee
Street address
Building No. 2, Research Council of Kermanshah University of Medical Sciences (KUMS), Shahid Beheshti Boulevard, Kermanshah, Iran
City
kermanshah
Province
Kermanshah
Postal code
6719851351
Approval date
2020-06-10, 1399/03/21
Ethics committee reference number
IR.KUMS.REC.1399.362

Health conditions studied

1

Description of health condition studied

Bed sore

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Bed sores status

Timepoint

Before the start of the study, 2 weeks after the start of the intervention

Method of measurement

Patients' wound status will be assessed using the Pressure Ulcer Scale for Healing Index.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Under a high-protein, high-calorie diet, along with two sachets per day (noon and evening) of dietary supplements containing L-glutamine, L-arginine and beta-hydroxybeta-methyl butyrate prepared by Karen Company of Iran (26 grams per sachet including 7.3 Grams of carbohydrates, 7 grams of L-arginine, 7 grams of L-glutamine and 1.5 grams of calcium beta hydroxy beta methyl butyrate)

Category

Treatment - Other

2

Description

Control group: Under a high-protein, high-calorie diet with placebo consumption

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Karam Ahmadian

Street address

Gomrek Street, Kermanshah, Iran

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6714897767

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

Street address

Building No. 2, Research Council Kermanshah University of Medical Sciences (KUMS), Shahid Beheshti Boulevard, Kermanshah, Iran

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Email

fnajafi@kums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Mehnoosh Samadi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Mehnoosh Samadi

Position

Associate professor

Latest degree

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Other areas of specialty/work

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

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Full name of responsible person

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Position

Student

Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Trail that began to fall ill on 22 Th. August of 2020 should have a release plan when recording its study protocol

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

No - There is not a plan to make this available