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 bedsore 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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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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Province
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6715847141
Phone
+98 83 3837 6892
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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
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Associate professor
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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