Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of protein supplement on paraspinal muscles in patients undergoing lumbar posterior spine fusion surgery

Protocol summary

Study aim

Overall purpose Effect of Protein Supplementation on Para Spinal Muscles in Lumbar Spine Posterior Fusion Surgery Specific goals 1. Evaluation and Comparison of Thickness of Paraspinal Muscle with CT Scan 2. Evaluation and comparison of degree and severity of paraspinal muscle mass atrophy with CT scan

Design

A randomized, controlled, double-blind, placebo-controlled clinical trial

Settings and conduct

Intervention patients will receive 36 grams of protein supplement along with diet containing 1.2 g/kg/day of protein for 30 days after surgery and control patients will receive maltodextrin along with diet containing 1.2 g/kg/day of protein 30 days after surgery. Patients will be evaluated for occurrence of paraspinal muscles after 3 months surgery. Masking: Triple (Participant, Investigator, Outcomes Assessor)

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Adult patients 18-65 years;Body mass index 18.5-30;Candidate for the elective posterior spine fusion. Exclusion Criteria: history of severe liver disorder; history of Kidney disorder;history of diabetes; smoking;Without history of neuromuscular diseases such as dystrophies and neurological disorders.

Intervention groups

Intervention: protein diet (1.2 g/kg/day) and protein supplement (36 g/day) for 1 month after surgery. Placebo : protein diet (1.2 g/kg/day) and maltodextrin for 1 month after surgery.

Main outcome variables

The thickness of the paraspinal muscles (multifidus, erector spinae, Quadratus, and Lumborum) in CT scan

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200301046655N1**
Registration date: **2020-03-14, 1398/12/24**
Registration timing: **prospective**

Last update: **2020-03-14, 1398/12/24**
Update count: **0**

Registration date

2020-03-14, 1398/12/24

Registrant information

Name

Razieh Khalooeifard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8895 5975

Email address

shkhalooei1367@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-08, 1399/01/20

Expected recruitment end date

2020-06-09, 1399/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of protein supplement on paraspinal muscles in patients undergoing lumbar posterior spine fusion surgery

Public title
The effect of protein supplement on paraspinal muscles in spine surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study Candidate for Posterior Lumbar Spine Fusion Elective Surgery
Exclusion criteria:
Severe liver disorder Severe renal disorder Osteoporosis (T score ≤ 2.5) Spinal trauma and fracture Diabetes Gastrointestinal malabsorption Parathyroid gland disorders Any neuromuscular disease such as dystrophies and neurological disorders smoking Use of drugs that affect bone metabolism, such as calcitonin, bisphosphonate, corticosteroids
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
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
Simple randomization, Random number table
Blinding (investigator's opinion)
Triple blinded
Blinding description
The patient, researcher, surgeon, nurse, and study analyzer will be blind to the intervention (protein supplement) and control (maltodextrin) groups. The supplements (protein and maltodextrin) are made by the manufacturer (Karen Iran) in a very similar packaging and only the code in each package specifies which protein and maltodextrin that will inform our company at the end of the study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

1

Registry name
ClinicalTrials.gov
Secondary trial Id
NCT04300517
Registration date
2020-03-05, 1398/12/15

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Vice-Chancellor in Research Affairs - Shahid Beheshti University of Medical Scie
Street address
Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town,
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2020-02-16, 1398/11/27
Ethics committee reference number
IR.SBMU.RETECH.REC.1398.802

Health conditions studied

1

Description of health condition studied
patients undergoing lumbar posterior spine fusion surgery
ICD-10 code
M51.17
ICD-10 code description
Intervertebral disc disorders with myelopathy, lumbar region

Primary outcomes

1

Description
Paraspinal Muscle Thickness
Timepoint
Baseline and 3 months after surgery
Method of measurement
computed tomography scan

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 3 Sachet Pure protein (15 g per sachet contains 12.6 grams of protein, 1 g carbohydrates, 0.4 g fat, 58 calories, Karen Iran) after

surgery up to a month after surgery

Category

Treatment - Surgery

2

Description

Control group: protein diet (1.2 g/kg/day) and maltodextrin for 1 month after surgery.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Tajrish hospital

Full name of responsible person

Dr Saeed Oraee Yazdani

Street address

Tajrish Sq

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Vice-Chancellor in Research Affairs

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Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town,

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ethics@behdasht.gov.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Razieh Khalooeifard

Position

student

Latest degree

Master

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

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Position

Associate professor

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Person responsible for updating data

Contact

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Position

student

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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

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

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

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available