

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 \leq 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,

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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

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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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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

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Latest degree

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Other areas of specialty/work

Nutrition

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Tehran

Province

Tehran

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