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Study of a milk protein supplement to help recovery after hip or knee replacement surgery

Submission date
22/03/2026

Recruitment status
No longer recruiting

Registration date
23/03/2026

Overall study status
Completed

Last Edited
23/03/2026

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
This study looked at whether a milk protein supplement could help people recover better after hip or knee replacement surgery. The supplement, called milk protein concentrate, is designed to support muscle strength and reduce inflammation. Researchers wanted to find out if adding this supplement to a person's usual diet could improve their mobility, muscle mass, and general recovery after surgery.

Who can participate?
Adults aged 45 to 85 years who were scheduled for a planned hip or knee replacement at the 424 General Military Training Hospital in Greece could take part. They had to be able to give informed consent and follow the study instructions. People could not join if they had allergies to milk or soy proteins, severe kidney problems, certain autoimmune or neurological conditions, active infections, dementia, or if they were having revision surgery.

What does the study involve?
Participants were placed into one of two groups. Both groups received the same amount of daily protein, but one group received part of their protein intake in the form of the milk protein supplement. This was taken twice a day by mixing the powder with drinks such as milk, kefir, or juice. All participants followed a standard physiotherapy programme after surgery. Researchers measured strength, walking speed, balance, muscle mass, and markers of inflammation before surgery and again 15 weeks later.

What are the possible benefits and risks of participating?
Taking part might help improve recovery after surgery by supporting muscle strength and reducing inflammation. However, this could not be guaranteed. Risks included possible digestive discomfort or allergic reactions, especially for people sensitive to milk or soy proteins. The study excluded anyone with known allergies to reduce this risk

Where is the study run from?
The study was carried out at the 424 General Military Training Hospital in Thessaloniki, Greece.

When is the study starting and how long is it expected to run for?
Participants were first enrolled on 9 May 2023, and the final participant was enrolled on 18 November 2024. The study was completed on 20 April 2025.

Who is funding the study?
The study is funded by the International Hellenic University, Greece.

Who is the main contact?
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Study information

Scientific Title
The effect of Milk Protein Concentrate (MPC) supplementation on functional recovery, muscle strength, and inflammatory markers in elderly patients following total hip or knee arthroplasty: A randomized controlled trial

Study objectives
To evaluate the role of a combined Milk Protein Concentrate (MPC) with essential minerals (Calcium and Phosphorus),(Protifar, Nutricia), in supporting muscle and overall recovery in orthopaedic patients.

Ethics approval required
Ethics approval required

Ethics approval(s)
submitted 31/07/2023, Scientific Council of the 424 General Military Training Hospital (424 GSNE). (Ring Road, Nea Efkarpia, Thessaloniki, 56429, Greece; +2310381000; 424-gsne@army.gr), ref: 6th Topic, Scientific Council Session July 2023/ 424 Military Hospital of Thessaloniki

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Supportive care

Study type(s)

Health condition(s) or problem(s) studied
Osteoarthritis, knee or hip arthroplasty

Interventions
The intervention consists of oral nutritional supplementation with Protifar (Nutricia), a high-protein Milk Protein Concentrate (MPC) powder. The formula features a low sodium and potassium profile and a specific Calcium-to-Phosphorus (Ca/P) ratio of 1.9:1, optimized for bone and muscle recovery. The omega-6 to omega-3 (n-6/n-3) ratio is 3.3:1, with trace amounts of total fat to avoid interference with systemic inflammation markers. The solution exhibits low osmolality (25 mOsm/L), ensuring high gastrointestinal tolerance. The product is officially notified to the Greek National Organization for Medicines (EOF, Prot. No. 81732/13-11-2009). Dietary caloric intake is standardized for both groups. Total protein intake is set at 1.3 g/kg/day for all participants.
Participants were allocated to the intervention and control groups using a computer-generated random sequence (1:1 ratio) created via Microsoft Excel.

Intervention Group (IG): 30g of the daily protein requirement is provided via the MPC formula, administered in two equal doses of 15g (at breakfast and 30 minutes post-physiotherapy). Each dose is diluted in 50 ml of water and added to milk, kefir, or juice to ensure compliance.

Control Group (CG): Receives the same total protein intake (1.3 g/kg/day) solely through standard hospital meals, without the specific MPC supplementation."
Dietary caloric intake is standardized for both groups, with total protein intake set at 1.3 g/kg /day. For the Intervention Group (IG), 30g of this daily requirement is administered in the form of a milk protein concentrate (MPC) formula, divided into two equal doses: 15g with breakfast and 15g approximately 30 minutes after the physiotherapy session. Each dose is diluted in 50 ml of water and subsequently added to milk, kefir, or juice to ensure compliance and palatability. The Control Group receives the same total protein intake (1.3 g/kg/day) through standard meals without the specific MPC supplementation.

IG and CG followed a standardized early physical therapy program, which focused on isometric exercises and progressive resistance training. The CG and IG were recruited during different, non-overlapping time periods. This design ensured that the groups remained independent.

The total duration of the intervention, including the follow-up period, was 15 weeks for both study arms.

Intervention Type
Supplement

Primary outcome(s)
1. Functional performance measured using handgrip strength(kgr); endurance (4 meters gait speed (m/sec); static balance (Single leg stance test(sec); time for 5 repetitions sit to stand test (sec) at 24 hours before surgery and 15 weeks post-operatively

2. Skeletal Muscle Mass(kgr); Lean Mass (kgr) measured using Bioelectrical Impedance Analysis (kgr) at 24 hours before surgery and 15 weeks post-operatively

Key secondary outcome(s))
1. Inflammation measured using C Reactive Protein in serum(mg/dL) at 24 hours before surgery and 15 weeks post-operatively

2. Oxidative Stress measured using 8-Isporostane in plasma and urine(pg/ml) at 24 hours before surgery and 15 weeks post-operatively

3. Clinical and biochemical data, including blood and urine analysis (CRP and 8-isoprostane levels), as recorded in the study’s structured assessment forms. These measures are part of the protocol approved by the Scientific Council of the 424 General Military Training Hospital (Session July 2023, 6th Topic), evaluating the impact of the MPC nutritional intervention (notified to EOF, Prot. No. 81732/13-11-2009)." measured using 8-Isporostane in plasma and urine(pg/ml) and CRP (mg/dl) at 24 hours before surgery and 15 weeks post-operatively

Completion date
20/04/2025

Eligibility

Key inclusion criteria
1. Adults aged 18 years and over
2. Scheduled for elective primary total hip or knee arthroplasty at 424 General Military Hospital
3. Ability to provide written informed consent and willingness to comply with the nutritional supplementation protocol and follow-up assessments

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
45 years

Upper age limit
85 years

Sex
All

Total final enrolment
88

Key exclusion criteria
1. Known allergy to milk and soy proteins or severe lactose intolerance
2. Severe renal impairment or kidney disease
3. Autoimmune diseases , Cognitive impairment, dementia, or psychiatric disorders , neuro-muscular disorders
4. Rheumatoid arthritis or active infection
5. Revision surgery

Date of first enrolment
09/05/2023

Date of final enrolment
18/11/2024

Locations

Countries of recruitment
Greece

Sponsor information

Organisation
International Hellenic University

ROR
https://ror.org/00708jp83

Funder(s)

Funder type

Funder Name
International Hellenic University

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available