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Higher protein intake after intensive care

Submission date	Recruitment status	[X] Prospectively registered
27/03/2026	Recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/05/2026	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
27/05/2026	Nutritional, Metabolic, Endocrine	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Critically ill patients experience severe and rapid muscle loss during intensive care unit (ICU) stay. The optimal nutrition support strategy after ICU discharge to support recovery of physical function is unknown. This study aims to investigate the effect of higher protein intake on muscle mass and physical function after intensive care.

Who can participate?
Patients admitted to the study center's ICU who remain in the ICU for at least 3 days, and receive invasive mechanical ventilation for 2 days. Study participants are enrolled on ICU discharge.

What does the study involve?
Participants are randomized to a protein target of either 2.0 grams/kg/day or 1.2 grams/kg/day, with similar energy targets. During hospital stay, an ICU dietitian will review the patient's nutrition 2-3 times per week and support the ward in achieving the allocated protein target. After hospital discharge, participants in both groups will receive telephone counseling by the study dietitian every 1-2 weeks. Participants in the high protein group also get home deliveries of high protein supplements to augument protein intake. Around 90 days after ICU discharge, participants are followed up with an assessment of muscle mass, physical function tests and self-rated health.

What are the possible benefits and risks of participating?
Participants in both trial arms will receive frequent dietitian counseling which is expected to result in better overall adherence to energy and protein targets compared to standard care. Similar strategies have been demonstrated to improve morbidity and survival in non-critically ill, hospitalized patients. Potential risks involve adverse medical effects of a higher-than-normal protein intake, which may be harmful for renal functions in some circumstances. To minimize this risk, patients with moderate-severe renal impairment are excluded from study participation.

Where is the study run from?
The study sponsor is Region Stockholm (Stockholm County Council, a government body in Sweden). The study will be performed at Karolinska University Hospital Huddinge, in Stockholm Sweden.

When is the study starting and how long is it expected to run for?
May 2026 to June 2027.

Who is funding the study?
The study is funded by an unrestricted grant from Dr. P Håkansson's Stiftelse. The primary investigator's research time is also funded by a salary grant from Region Stockholm.

Who is the main contact?
The main contact for the study is the primary investigator, Martin Sundström Rehal, martin.sundstrom-rehal@regionstockholm.se

Contact information

Type(s)
Public

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Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title
Higher versus standard protein targets in post-intensive care unit patients: a randomised, unblinded parallell group feasibility trial

Acronym

HiPPIe

Study objectives
The main study objective is to determine the feasibility of a randomized controlled trial investigating a high versus standard protein target for up to 90 days after ICU discharge.

Secondary objectives include documenting the effects of a higher versus standard protein target after ICU discharge on physical function, nutritional status and other patient-centered outcome measures.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/10/2025, Swedish Ethical Review Authority (Etikprövningsmyndigheten Box 2110, Uppsala, 750 02, Sweden; +46 010-475 08 00; registrator@etikprovning.se), ref: 2025-05679-01

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Dose comparison

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
The effect of post-intensive care unit nutrition support on recovery after critical illness.

Interventions
Patients expected to be discharged from ICU within 72 hours are screened for inclusion. After obtaining informed consent, study subjects are randomised to one of the two treatment arms:

- Intervention: Daily protein target of 2.0 g/kg for up to 90 days after ICU discharge.
- Control: Daily protein target of 1.2 g/kg for up to 90 days after ICU discharge.
The trial assignment is open label. Guidelines for energy targets are equivalent between groups.

All participants will be assessed by a study dietitian to determine the optimal route and composition of feeding to achieve nutritional targets. Within 72 hours from ICU discharge, body composition will be determined by weight (kg), an ultrasonographic measurement of quadriceps

muscle layer thickness (cm) and bioimpedance analysis. Medical Research Council Sum Score and grip strength by hand dynamometry will also be tested at baseline.

During hospitalization, nutritional intake (oral, enteral and parenteral) will be documented daily and reviewed by the study dietitian two to three times weekly to determine the adequacy of current feeding strategies, with revised recommendations as appropriate. Biochemical markers of inflammation and renal function will be monitored at a frequency consistent with usual care on the admitting ward and documented in the eCRF.

After hospital discharge, participants will receive telephone consultations with the study dietitian every 1-2 weeks to review the adequacy of protein and energy intake. Participants in the high-protein group will also receive home deliveries of high protein oral nutrition supplements corresponding to a daily intake of 0.8 g/kg. A more extensive review of home intake is performed 2-3 times during outpatient follow-up with a 3-day food diary.

Intervention Type
Supplement

Primary outcome(s)
1. Average daily protein intake measured using a daily recorded intake during hospitalization; after hospital discharge: dietitian telephone assessment with last observation carried forward. i) detailed food diary during first 1-2 weeks, ii) 24 hour recall every following 1-2 weeks, iii) detailed food diary during last 1-2 weeks prior to 90 day follow-up, iv) difference between delivered and returned oral nutrition supplements (not consumed) at 90 days after ICU discharge.

Key secondary outcome(s)
1. Time to index hospital discharge measured using hospital electronic medical records at 90 days after ICU discharge.

2. Readmission to hospital measured using hospital electronic medical records at 90 days after ICU discharge.

3. Activities of daily living measured using ADL/IADL at 90 days (+/- 2 weeks) after ICU discharge.

4. Clinical frailty score measured using the clinical frailty scale instrument at 90 days (+/- 2 weeks) after ICU discharge

5. Quality of life measured using the Euro-EQ-5D-5L instrument at 90 days (+/- 2 weeks) after ICU discharge

6. Physical function measured using 30 second sit to stand test (repetitions), 6 minute walk test (m) and hand grip strength (kg) at 90 days (+/- 2 weeks) after ICU discharge.

7. Nutritional status measured using the GLIM criteria at 90 days (+/- 2 weeks) after ICU discharge.

8. Renal function measured using plasma and urinary creatinine, plasma urea, urinary nitrogen and proteinuria at 90 days (+/- 2 weeks) after ICU discharge.

9. Survival status measured using hospital electronic medical records at 90 days after ICU discharge.

10. Quadriceps muscle thickness (cm) measured using ultrasound measurement at ventral midpoint of thigh at 90 days (+/- 2 weeks) after ICU discharge.

11. Body composition measured using bioimpedance analysis at 90 days (+/- 2 weeks) after ICU discharge.

Completion date
30/06/2027

Eligibility

Key inclusion criteria
1. 18 years or older
2. ICU length of stay >72 hours
3. Received invasive mechanical ventilation for 48 hours or more
4. Received enteral or parenteral nutrition during ICU stay
5. Discharged or expected to be discharged alive from ICU within 72 hours of enrollment

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Inability to provide informed consent
2. > 72 hours between ICU discharge and enrollment
3. Inherited or acquired disorders of amino acid metabolism where high protein intake is contraindicated
4. Central nervous system injury (prior to or during hospitalisation) with impaired lower limb motor function expected to interfere with outcome assessment
5. Pre-existing cognitive impairment or language barrier expected to prevent outcome assessment or informed consent
6. Primary neuromuscular disease (e.g. myasthenia gravis, Guillanne Barré, multiple sclerosis with impaired lower limb motor function)
7. Severe lower limb arterial insufficiency expected to prevent outcome assessment
8. Lower extremity impairments (e.g. amputation, fractures, arthritis) preventing outcome

assessment
9. Morbid obesity where subcutaneous adipose tissue prevents visualisation on muscle ultrasound
10. Expected dealth during hospitalisation or limitations in treatment to best supportive care
11. CAM-ICU positive on screening (patient can be screened again if delirium resolves)
12. Milk protein allergy
13. Unable to walk independently prior to acute illness resulting in ICU admission (walking aid permitted)
14. Renal insufficiency with eGFR < 45ml/min/1.73m2
15. Decompensated cirrhosis with hepatic encephalopathy
16. Treating physician at receiving ward does not consider randomisation to treatment targets to be in the best interest of the patient
17. Acute or chronic macronutrient malabsorption (i.e. high output ileostomy, intestinal failure) where the physician responsible for the patient's short or long-term care does not consider randomisation to treatment targets to be in the best interest of the patient
18. Pregnancy

Date of first enrolment
25/05/2026

Date of final enrolment
30/06/2027

Locations

Countries of recruitment
Sweden

Study participating centre
Karolinska University Hospital Huddinge
-
-
Sweden
-

Sponsor information

Organisation
Karolinska University Hospital

ROR
https://ror.org/00m8d6786

Funder(s)

Funder type

Funder Name
Dr Per Håkanssons stiftelse

Alternative Name(s)
Dr. Per Håkansson Foundation, Dr P Håkanssons Stiftelse

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Sweden

Funder Name
Stockholms Läns Landsting

Alternative Name(s)
Stockholm County Council

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available