

Rehabilitation after a hip fracture: the effects of dietary protein and exercise on bone and muscle health and quality of life

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This intervention study investigates the effectiveness, costs and cost-effectiveness of a protein-enriched diet and resistance exercise training for 3 months on bone and muscle health, and quality of life in older adults recovering from an acute hip...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON49870

Source

ToetsingOnline

Brief title

ProBUS study

Condition

- Fractures

Synonym

broken hip, Hip fracture

Research involving

Human

Sponsors and support

Primary sponsor: Wageningen Universiteit

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Bone, Hip fracture, Muscle, Protein

Outcome measures

Primary outcome

- * Bloodmarkers: P1NP, IGF-1, PTH
- * Bone mineral density: total hip, femoral neck, and total body
- * Physical performance
- * Muscle mass

Secondary outcome

- * Quality of life
- * Inpatient rehabilitation time
- * Daily life functioning
- * Fear of falling
- * Stress
- * Levels of (free) 25(OH)D, folate, vitamin B12, and vitamin C

Study description

Background summary

A hip fracture jeopardizes the health status and quality of life of older adults. Only half of the patients regain their pre-fracture functional level and 24% dies within the following year. The risk of reoccurring fractures and increased mortality persists for at least 10 years following the initial fracture. Targeting modifiable risk factors, such as osteoporosis and sarcopenia, are therefore a major area of interest. A high protein intake and resistance exercise may be beneficial for older hip fracture patients, it may improve clinical outcomes, and slow down postoperative bone and muscle loss.

The current study will investigate a unique study population; not much attention is given to the rehabilitation as setting.

Study objective

This intervention study investigates the effectiveness, costs and cost-effectiveness of a protein-enriched diet and resistance exercise training for 3 months on bone and muscle health, and quality of life in older adults recovering from an acute hip fracture.

Study design

This study will be a 3-month randomized, controlled, parallel-group trial.

Intervention

There will be two groups, an intervention group receiving a tailor-made protein-enriched diet and an extended exercise training program, and a control group receiving usual care.

Study burden and risks

Following a protein-enriched diet for 3 months requires an adaption in the subjects* dietary habits, but these changes will be tailor-made by consultation with a dietician in order to make the subjects feel comfortable with the diet. Most measurements are part of usual care and are therefore considered to impose no extra burden on subjects. A protein intake of 1.5 g/kg bw/d is safe and probably needed for both bone and muscle health in our study population, as recommended by several expert groups. People with disorders/diseases where a high protein intake can be harmful will be excluded from the study. Concerning the benefits, this study will lead to knowledge about the impact of protein and exercise on bone and muscle health outcomes in older adults. It is hypothesized that a higher protein intake and resistance exercise training have a beneficial effect on bone and muscle health outcomes and subsequently leads to a shorter rehabilitation time and a better quality of life.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Elderly (65 years and older)

Inclusion criteria

- * Age $\geq$ 65 years
- * Acute hip fracture
- * Able to give written informed consent
- * Mentally competent, as judged by the treating physician
- * Admission to a rehabilitation centre that participates in this research

Exclusion criteria

- * Allergic, intolerant or hypersensitive to milk/lactose (self-reported)
- * Not willing to stop using dietary supplements with the exception of calcium and vitamin D
- * Pathological fracture or periprosthetic fracture
- * Abnormal hepatic or renal laboratory parameters, such as estimated glomerular filtration rate (eGFR) <30 ml/min/1,73 m² (data from hospital)
- * Diagnosis of disorders/diseases where a high protein intake can be harmful, such as renal impairment or failure, or liver disease (elderly care physician has the decisive voice).
- * Diagnosis of bone metabolic disorders such as primary hyperparathyroidism, Paget's disease, or myeloma
- * Taking medication other than bisphosphonates known to strongly alter bone, calcium or muscle metabolism, such as oestrogen, hormone replacement therapy,

corticosteroids, anabolic agents or calcitonin.

* Disorders/diseases which may affect ability to follow study protocol and which cannot be overcome with help of a caregiver

* Current participation in other scientific research

* No permission to request information from the general practitioner/ treating specialist(s) about medical history, medication use, liver and kidney values, and details about the broken hip

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	30-09-2024
Enrollment:	102
Type:	Actual

Ethics review

Approved WMO	
Date:	29-04-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	18-08-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	

Date:	13-05-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	18-09-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 22171
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL68932.081.19
Other	NTR: NL7554