Protein for Bone and mUScle health in hip fracture patients

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It is hypothesized that a higher protein intake has a beneficial effect on bone and muscle health outcomes and subsequently leads to a shorter rehabilitation time.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22171

Source
Nationaal Trial Register

Brief title
ProBUS study

Health condition

Acute hip fracture

Sponsors and support

Primary sponsor: Division of Human Nutrition and Health of Wageningen University & Research
Source(s) of monetary or material Support: Jaap Schouten Foundation

Intervention

Outcome measures

Primary outcome

● Markers of bone turnover: CTX and P1NP ● BMD: total hip, femoral neck, and total body ●

IGF-1 levels ● Physical performance ● Muscle mass

Secondary outcome

● Inpatient rehabilitation time ● Sarcopenia prevalence ● Daily life functioning ● Quality of life

Study description

Background summary

Rationale: 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 may be beneficial for older hip fracture patients, it may improve clinical outcomes, slow down postoperative bone and muscle loss. The current study will investigate a unique study population as not much attention is given to the rehabilitation as setting. Objective: This intervention study investigates the effect of a protein-enriched diet for 6 months on bone health, muscle mass and physical performance in older adults recovering from an acute hip fracture. Study design: This study will be a 6-month randomized, single-blind, controlled, parallel-group trial. Study population: Adults aged 65 years and older recovering from an acute hip fracture. Intervention: There will be two groups, an intervention group receiving a tailor-made protein-enriched diet and a control group receiving usual care. Main study parameters/endpoints: The primary study parameters are markers of bone turnover (serum C-terminal telopeptide of type I collagen and procollagen type 1 N propeptide), bone mineral density, insulin-like growth factor 1 levels, muscle mass, and physical performance. Secondary parameters include rehabilitation time, sarcopenia prevalence, daily life functioning, and quality of life. Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Following a protein-enriched diet for 6 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 on bone and muscle health outcomes in older adults. It is hypothesized that a higher protein intake has a beneficial effect on bone and muscle health outcomes and subsequently leads to a shorter rehabilitation time.

Study objective

It is hypothesized that a higher protein intake has a beneficial effect on bone and muscle health outcomes and subsequently leads to a shorter rehabilitation time.

Study design

Baseline, discharge from rehabilitation center, 3 and 6 months

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

● Age ≥ 65 years ● Acute hip fracture ● Able to give written informed consent ● 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 exception of calcium and vitamin D ● Pathological 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, liver disease, or diabetes associated with nephropathy (geriatric care physician has the decisive voice). ●

Diagnosis of bone metabolic disorders such as primary hyperparathyroidism, Paget’s disease, or myeloma ● Taking medication known to strongly alter bone or calcium metabolism, such as oestrogen, hormone replacement therapy, corticosteroids, anabolic agents, calcitonin, or bisphosphonates ● 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:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2019
Enrollment:	102
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	25-02-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49870
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7554
CCMO	NL68932.081.19
OMON	NL-OMON49870

Study results