Protein turnover in the osteoarthritic knee; the impact of preoperative protein intake.

Published: 05-12-2016 Last updated: 14-03-2025

To investigate the effect of preoperative protein supplementation on Hoffa*s fat pad, synovium, tendon, bone, muscle, ligament, menisci, and cartilage protein synthesis of the OA knee.

Ethical review	Approved WMO
Status	Completed
Health condition type	Protein and amino acid metabolism disorders NEC
Study type	Interventional

Summary

ID

NL-OMON54781

Source ToetsingOnline

Brief title KneeT

Condition

- Protein and amino acid metabolism disorders NEC
- Joint disorders

Synonym Knee osteoarthritis, Osteoarthritis of the knee

Research involving Human

Sponsors and support

Primary sponsor: Universiteit Maastricht Source(s) of monetary or material Support: Ministerie van OC&W

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Intervention

Keyword: Musculoskeletal tissues, Osteoarthritis of the knee, Protein synthesis, Protein turnover

Outcome measures

Primary outcome

Primary study parameters include protein synthesis rates and enrichments of

Hoffa*s fat pad, synovium, tendon, bone, muscle, ligament, menisci, and

cartilage.

Secondary outcome

Secondary parameters include whole-body protein synthesis, breakdown,

oxidation, and net balance.

Study description

Background summary

Osteoarthritis (OA) of the knee is a common cause of pain and disability, especially in people over the age of 65. In the current health care system both conservative (e.g. intra-articular injections with corticosteroids) and surgical (total knee replacement, TKR) treatment are applied. It is well known that maintenance of different tissues is determined by a dynamic balance between protein synthesis and breakdown rates, with temporary changes in either protein synthesis or breakdown allowing net protein accretion or loss. Though protein supplementation has shown to be an effective nutritional strategy in stimulating muscle protein synthesis, it remains unclear to what extent other musculoskeletal tissues are able to respond to dietary protein supplementation. Therefore, the current study assesses the impact of preoperative protein supplementation on protein synthesis in different musculoskeletal tissues of the knee. This proposal is based and builds on METC application 12-3-058, 12-3-059, 15-3-019 and 14T165.

Study objective

To investigate the effect of preoperative protein supplementation on Hoffa*s fat pad, synovium, tendon, bone, muscle, ligament, menisci, and cartilage

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protein synthesis of the OA knee.

Study design

Randomized, parallel (three groups) study design in which the intervention group will be compared to the control group.

Intervention

Pre-sleep protein supplementation two weeks before TKR, or no intervention.

Study burden and risks

The risks involved in participating in this study are minimal. There are no potential effects known for the ingestion of protein. Muscle biopsies and tissue collection will be performed during the surgical procedure.

Contacts

Public Universiteit Maastricht

Universiteitssingel 50 Maastricht 6229ER NL **Scientific** Universiteit Maastricht

Universiteitssingel 50 Maastricht 6229ER NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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Age

Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

- Written informed consent
- Male and female patients scheduled for total knee arthroplasty
- BMI between 18.5-35 kg/m2
- Age >18 years
- Mentally competent, as judged by the treating physician
- Functioning gastrointestinal tract, eligible for oral protein supplementation

Exclusion criteria

- Corticosteroid injections less than 3 months prior to participation
- Any medications know to affect protein metabolism (i.e. systemic
- corticosteroids or prescription strength acne medications)
- Lactose intolerance
- Insulineafhankelijke diabetes mellitus
- Alcohol abuse
- Rheumatoid arthritis
- Peripheral artery disease Fontaine III or IV
- COPD GOLD III or IV
- Pheynylketonuria
- Surgical intervention to the knee in the past four weeks
- Total parenteral nutrition at day of surgery
- Neoadjuvant chemotherapy or radiotherapy
- GFR <20 mL/min/1.73 m2
- Osteoarthritis of the knee secondary to septic arthritis, osteonecrosis, fracture, OD, or malignant processes
- Collagen disorders, e.g. Marfan and Ehler-Danlos
- Any other medical condition that may interfere with the safety of the subjects or the outcome parameters, in the investigators judgement
 Investigator*s uncertainty about the willingness or ability of the subject to
- comply with the protocol instructions
- Participation in any other studies involving investigational or marketed products concomitantly or within two weeks prior to entry into the study

Study design

Design

Interventional
Parallel
Randomized controlled trial
Open (masking not used)

Primary purpose: Basic science

Recruitment

NL	
Recruitment status:	Completed
Start date (anticipated):	04-06-2019
Enrollment:	24
Туре:	Actual

Ethics review

Approved WMO	
Date:	05-12-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	12-07-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	06-02-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	06-04-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO	
Date:	19-11-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	10-06-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	17-04-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register CCMO ID NL58921.068.16