The effect of collagen supplementation on collagen metabolism after total hip arthroplasty.

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We aim to determine the effects of collagen supplementation on biomarkers of collagen metabolism in the two weeks following total hip arthroplasty in older adults with osteoarthritis.

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

Summary

ID

NL-OMON54316

Source
ToetsingOnline

Brief title
CoMet-Hip

Condition

- Protein and amino acid metabolism disorders NEC
- Joint disorders
- Bone and joint therapeutic procedures

Synonym
Hip osteoarthritis, Osteoarthritis of the hip

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Collagen metabolism, Collagen protein, Osteoarthritis, Total hip arthroplasty

Outcome measures

Primary outcome

The main endpoints of this study are the changes in serum concentrations of biomarkers of collagen metabolism perioperatively and up to two weeks after surgery. These biomarkers represent bone and cartilage synthesis (N-terminal propeptide of type I and type II collagen, respectively: P1NP, P2NP) and breakdown (C-terminal telopeptide of type I and type II collagen, respectively: CTx1, CTx2).

Secondary outcome

Secondary endpoints include changes in plasma amino acid concentrations.

Study description

Background summary

Osteoarthritis is a highly prevalent degenerative disease characterized by disturbances in the collagenous tissues of joints (e.g. cartilage, bone) that leads to pain, functional decline and reduced quality of life. Although the onset of the disease can be linked to a number of causes such as injury or overuse, the most prominent risk factor of osteoarthritis is age. The (partial) replacement of joints (i.e. arthroplasty) is a common surgical procedure performed on patients with osteoarthritis when other treatment options are insufficient. During arthroplasty, damaged cartilage and bone are removed and replaced with prostheses in order to improve function and reduce pain. Despite the prevalence of this procedure, it is not yet well established what occurs to collagen metabolism perioperatively and in the early stages of recovery. Such knowledge could provide relevant insight for improving treatment to support post-operative healing. One such treatment option could be collagen supplementation, which has been shown to boost collagen synthesis in healthy

individuals. However, the effect of collagen supplementation on collagen metabolism during recovery from arthroplasty remains to be investigated.

Study objective

We aim to determine the effects of collagen supplementation on biomarkers of collagen metabolism in the two weeks following total hip arthroplasty in older adults with osteoarthritis.

Study design

This is a double-blind placebo-controlled intervention study.

Intervention

This study involves a 2-week nutritional intervention in which the participants will be randomly allocated into an intervention group (HC), receiving daily supplementation of 15g hydrolysed collagen with 48mg vitamin C, or a placebo group (PLA), receiving an energy-matched supplementation of 15g maltodextrin with 48mg vitamin C.

Study burden and risks

Participation in this study poses minimal risk. The subjects will receive a blood draw on five occasions; the first (baseline, day 0), second (during surgery, day 0), and third (morning after surgery, day 1) samples are taken via an infusion line that is already placed as of standard in-hospital treatment procedures (no additional burden), and the fourth (day 4), and the last blood draw (day 15) will be additional to *standard care procedures*. Participants will have to consume a daily supplement for 2 weeks and will be asked to record dietary intake for 3 days, which may be seen as burdensome. The beverage for both groups contains 48mg vitamin C, which is not associated with negative side effects. The intervention group will ingest 15g hydrolysed collagen protein daily, which is well tolerable and may have a facilitatory role in the recovery process. The placebo group will receive 15g maltodextrin daily, which is well tolerable and has no adverse effects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Written informed consent
• With osteoarthritis and due for total hip arthroplasty
• >= 60 years old
• BMI 18.5-35 kg/m2

Exclusion criteria

• Taking medications known to influence protein metabolism
• Collagen allergy
• Diabetes mellitus
• Alcohol abuse
• Surgical intervention in past four weeks
• GFR <20mL/min/1.73m2
• Rheumatoid arthritis
• Collagen disorders
• Cancer
• Gastrointestinal disease

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-11-2022
Enrollment:	40
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	16-08-2021
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-07-2022
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	ID
CCMO	NL78139.068.21
Other	NL9608