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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27884

Source
Nationaal Trial Register

Brief title
CoMet-Hip

Health condition

Osteoarthritis of the hip

Sponsors and support

Primary sponsor: Maastricht University
Source(s) of monetary or material Support: NA

Intervention

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 and pain and functional outcomes.

Study description

Background summary

Total hip arthroplasty (THA) is a common procedure used to treat hip osteoarthritis (a degenerative disease affecting collagen-rich joint tissues). Little is known about the efficacy of post-operative nutritional intervention to aid recovery after THA. It is hypothesized that ingesting collagen protein may beneficially alter collagen metabolism. This study aims to assess the effect of post-operative collagen supplementation on biomarkers of collagen metabolism in the two weeks following THA in older adults with osteoarthritis. Forty older adults with osteoarthritis will be randomly allocated to receive daily supplementation of either 15g collagen protein or isocaloric placebo, with 48mg vitamin C during the two-weeks following THA. Biomarkers of collagen metabolism will be measured via blood samples, which will be taken before, during, 1 day after, 4 days after, and 15 days after THA. The primary endpoints are changes in serum concentrations of biomarkers of collagen metabolism before and after supplementation. Secondary endpoints are changes in plasma concentrations of amino acids as well as pain and functional outcomes. We expect that collagen supplementation will increase collagen synthesis and reduce collagen breakdown, which may suggest a therapeutic role of collagen ingestion to assist recover after total hip arthroplasty.

Study objective

Collagen supplementation will augment the increase in biomarkers of collagen synthesis compared to placebo in patients with osteoarthritis after total hip arthroplasty.

Study design

Blood will be collected at 5 time points:
1. Day of operation (pre);
2. During operation;
3. Day after operation;
4. Four days after operation;
5. Fourteen days after operation

Intervention

The intervention consists of two-weeks of (15g) daily collagen supplementation or isoenergetic placebo (maltodextrine) following total hip arthroplasty.

Contacts

Public
Maastricht University
Alejandra Monsegue

+31433881509
Scientific
Maastricht University
Alejandra Monsegue

+31433881509

Eligibility criteria

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2021
Enrollment:	40
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL9608
Other	METC azM/UM : METC 21-045

Study results