

Collagen digestion and amino acid absorption kinetics and the effect on muscle & skin connective tissue protein synthesis in vivo in humans

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To assess the impact of ingestion of collagen peptides on muscle connective tissue protein synthesis in vivo in humans.

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

Summary

ID

NL-OMON53526

Source

ToetsingOnline

Brief title

Codiak study

Condition

- Other condition

Synonym

Muscle connective tissue protein synthesis; muscle connective tissue buildup

Health condition

Digestie & absorptie, spier en huid

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W, Bedrijf; PB Leiner, PB Leiner

Intervention

Keyword: Collagen, Digestion, Muscle, Skin

Outcome measures

Primary outcome

The primary endpoint will be the muscle connective tissue protein synthesis over the period before and after intake of collagen protein peptides, as determined using stable isotope tracer methodology.

Secondary outcome

To quantify the digestion and absorption kinetics of collagen peptides and the subsequent impact on skin connective tissue protein synthesis rates in vivo in humans. Also, incorporation of collagen-derived amino acids in muscle & skin tissue will be determined. Other secondary outcomes include whole-body protein kinetics (total rate of appearance, exogenous rate of appearance, endogenous rate of appearance, rate of disappearance), whole-body protein metabolism (synthesis, breakdown, oxidation, net balance), overall plasma amino acid responses, postprandial hydroxyproline concentration over time (iAUC) and plasma insulin responses.

Study description

Background summary

Collagen protein is the central structural component of extracellular connective tissues within skeletal muscle, bone, cartilage and skin. Dietary collagen peptides are a promising protein source to deliver the specific amino acid precursors required to support an increase in connective tissue protein synthesis across several tissues (e.g. muscle, skin). However, the digestion and absorption kinetics of collagen peptides and the subsequent impact on muscle and skin connective tissue protein synthesis rates have not yet been assessed in vivo in humans.

Study objective

To assess the impact of ingestion of collagen peptides on muscle connective tissue protein synthesis in vivo in humans.

Study design

Clinical study with a single treatment pre-post design.

Intervention

All subjects will perform a single experiment where they ingest 40 g of collagen protein peptides in 400 mL water. Before and after ingestion, blood samples, muscle and skin biopsies will be taken at regular intervals during a 7.5 hour period.

Study burden and risks

The burden and risks with participation are small. A DEXA scan will be done to assess body composition, where the level of radiation is very low compared to the background radiation level in the Netherlands. Furthermore, we will ask the participants to fill out a medical questionnaire. Insertion of the catheters during the test day is comparable to a blood draw and could result in a small hematoma. We will take 12 blood samples during the experimental period. The total amount of blood we draw (120 mL) is much less than the amount of a blood donation (500 mL) and will be completely restored in approximately 1 month. Muscle and skin biopsies (both 3x) will be obtained under local anesthesia by an experienced physician. The muscle biopsy may cause some minor discomfort, which is comparable to muscle soreness or the pain one has after bumping into the corner of a table.

Participants will come to the university two times: 1 screening (~1h) and 1 experimental day (~8h). On the experimental test day, the subjects will be asked to remain fasted (with the exception of the experimental drinks). In addition, subjects will be asked in the two days prior to the test days not to perform any type of intense physical activity and to avoid consuming caffeine and alcohol in the 12h and 24h prior to the test days, respectively. Participants will be asked to record their nutritional intake and daily

activities in the two days prior to the experimental test days. There is no direct benefit to the participant, only their contribution to the scientific knowledge on digestion of collagen protein peptides and the effect on muscle and skin connective tissue protein synthesis rates. The protein supplements are produced according to food safety standards and are safe for human use.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Inclusion criteria

- Aged between 18-35 years
- Healthy, recreationally active (participating in recreational sports activities ≥ 1 and ≤ 6 h per week, with a maximum of 2 h resistance-type exercise)
- $18.5 \leq \text{BMI} \leq 30 \text{ kg/m}^2$
- No physical limitations (i.e. able to perform all activities associated with

daily living in an independent manner).

Exclusion criteria

- Smoking
- Musculoskeletal disorders
- Metabolic disorders
- Use of any medications known to affect protein metabolism (i.e. corticosteroids, non-steroidal anti-inflammatories, or prescribed acne medications).
- Chronic use of gastric acid suppressing medication or anti-coagulants
- Unstable weight over the last three months
- Diagnosed GI tract disorders or diseases
- Blood donation in the past 2 months

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 22-10-2024

Enrollment: 14

Type: Actual

Ethics review

Approved WMO

Date: 23-06-2022

Application type: First submission

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	16-04-2024
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	NL81239.068.22
Other	Registratie na goedkeuring METC