Effects of 10 gram collagen protein hydrolysate on cardiometabolic health in obese (BMI 25-35 kg/m2) men and women with elevated risk to develop Type-2 diabetes and CVD

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We here study the effect of a 10g/day collagen hydrolysate for a period of 4 weeks on glycemic control and cardiovascular health in a parallel design study using (BMI 25-35 kg/m2) men and women who are likely to have a disturbed lipid and glucose...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON56269

Source
ToetsingOnline

Brief title
Collagen peptides and glycemic control

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes, glucose metabolism

Research involving
Human

Sponsors and support

Primary sponsor: Voeding en Bewegingswetenschappen
Source(s) of monetary or material Support: bedrijf Peptan / Rousselot

Intervention

Keyword: cardiometabolic health, metabolism, nutrition, protein hydrolysate

Outcome measures

Primary outcome

Daily intake of 10 gram collagen protein hydrolysate by (BMI 25-35 kg/m2) men and women does not change glucose metabolism, as measured by change in average daily glucose concentrations measured over a 15 hours period between waking up and going to bed 7:00AM - 22:00PM for three days, which is calculated based on the total area under the curve (tAUC) over the entire 15 hours follow-up during these three days

Secondary outcome

To investigate if daily intake of 10 gram collagen protein hydrolysate by (BMI 25-35 kg/m2) men and women changes glucose metabolism, lipid metabolism and low-grade inflammation as measured by:

- Fasting serum lipids and lipoproteins (all blood samples);

- Fasting plasma glucose, insulin, and C-peptide concentrations and calculated HOMA-IR (all blood samples);

- Fasting low-grade inflammation plasma markers (hsCRP, IL6, IL8, TNFa)

- Postprandial glucose metabolism following a high-fat, high-carb meal;

- Postprandial TAG metabolism following a high-fat, high-carb meal;

To investigate if daily intake of 10 gram collagen protein hydrolysate by (BMI 25-35 kg/m2) men and women changes general well being as measured by:

- Quality of life, assessed with a 32-item questionnaire (including social, spiritual, emotional, cognitive, physical, activities of daily living, and integrated quality of life),

- Mood, degree of pleasantness and arousal, as assessed with the Affect grid.

- Fatigue as assessed using the FSS, a 9-item questionnaire that is used to determine the severity of fatigue a subject experienced in the past week during daily activities

- Cognitive performance, assessed with a validated neuropsychological test battery (CANTAB)

To investigate if daily intake of 10 gram collagen protein hydrolysate by (BMI 25-35 kg/m2) men and women changes vascular function as measured by:

- Venular and arteriolar diameters, assessed via fundus photography;

- Office blood pressure (each visit);

- 36-hour blood pressure profiles using wearables.

-- Cerebral blood flow, assessed using transcranial doppler ultrasound

Study description

Background summary

The worldwide incidence of Type 2 Diabetes Mellitus (Type2-DM) is rapidly growing. People with Type2-DM are at increased risk of developing long-term micro- and macrovascular complications. Type2-DM accounts for almost one in ten deaths around the world and up to 80% of these deaths are related to

cardiovascular disease. A functional food ingredient with the ability to improve glycemic control, which could translate into improved arterial stiffness, and/or the characteristics of the microcirculation, could potentially contribute to the delay or prevention of a range of cardiovascular diseases in the general population and could provide additional complimentary alternatives to pharmacological and lifestyle based interventions in the maintenance of cardiovascular health. Food-derived bioactive peptides represent a source of health-enhancing components that have been reported to have cardiovascular health benefits in humans and may be incorporated in functional foods. Up till now studies using collagen hydrolysates particularly addressed issues around joint health, however there are some preliminary indications that other health related targets might be affected as well. We here propose to focus on the potential effects of collagen hydrolysates on glycemic control and the consequent effects on arterial stiffness and characteristics of the microcirculation, both important parameters for the assessment of future cardiovascular disease (CVD) risk.

Study objective

We here study the effect of a 10g/day collagen hydrolysate for a period of 4 weeks on glycemic control and cardiovascular health in a parallel design study using (BMI 25-35 kg/m2) men and women who are likely to have a disturbed lipid and glucose metabolism and increased risk to develop CVD and/or Type2-DM.

Study design

During the intervention period, 30 subjects will consume the protein hydrolysate daily, while another group consumes a placebo (N=30). The primary outcome parameter of this study is a change in average daily glucose concentration measured over a 15 hours period between waking up and going to bed 7:00 AM - 22:00 PM for three consecutive days. Additionally, at the end of both the experimental periods, a postprandial test will be performed, in which blood will be sampled frequently (T0, T15, T30, T45, T60, T90, T120, T180, and T240) to study postprandial glucose and triacylglycerol responses. Finally, we evaluate changes in perceivable health benefits like the quality of life, mood, fatigue, cognitive performance and vascular function.

Intervention

During the intervention period, 30 subjects will consume 10 gram collagen protein hydrolysate daily, while another group consumes a placebo (N=30).

Study burden and risks

Subjects will be screened to determine eligibility during two visits of 15 minutes. During these screening visits, anthropometric measurements will be

performed and blood pressure will be determined. In addition, a venous blood sample (5.0 mL) will be drawn. During the study there will be 3 separate blood sampling moments and 2 postprandial test days where also blood is sampled. No direct health benefit for the study participants is expected. Investigational products are safe, and all ingredients to prepare the mixed meals for the postprandial test are commercially available and approved for human consumption. Sometimes the collagen hydrolysate may cause mild gastrointestinal discomfort. In total during the entire study 295 mL blood will be sampled (two screenings of each 5 mL, three times 25 mL fasting, 2 postprandial test days of 105 mL each). Some study subjects may report pain during venipuncture. Insertion of the cannula can cause some discomfort and possible a hematoma or bruise. Some subjects may also report pain during the insertion of the cannula. In principle, all measurements are routine in our metabolic research unit (MRUM) and are not expected to lead to physical side effects. Time investment for the participants is approximately 15 hours, excluding travel time.

Contacts

Public
Selecteer

Universiteitsingel 50
Maastricht 6229 ER
NL
Scientific
Selecteer

Universiteitsingel 50
Maastricht 6229 ER
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

- Aged between 40-75 years - Men and women - BMI between 25-35 kg/m2 - Serum total cholesterol < 8.0 mmol/L (further testing is recommended for excessive hyperlipidemia [serum total cholesterol >= 8.0 mmol/L] according to the Standard for cardiovascular risk management of the Dutch general practitioners community [NHG]) - Serum triacylglycerol < 4.5 mmol/L - No current smoker - No diabetic patients - No familial hypercholesterolemia - No abuse of drugs - Not more than 4 alcoholic consumption per day with a maximum of 21 per week?? - Stable body weight (weight gain or loss < 3 kg in the past three months) - No use of medication known to treat blood pressure, lipid or glucose metabolism - No use of an investigational product within another biomedical intervention in the previous month - No severe medical conditions that might interfere with the study, such as epilepsy, asthma, kidney failure or renal insufficiency, chronic obstructive pulmonary disease, inflammatory bowel diseases, auto inflammatory diseases and rheumatoid arthritis - No active cardiovascular disease like congestive heart failure or cardiovascular event, such as an acute myocardial infarction or cerebrovascular accident - Willingness to give up being a blood donor from 8 weeks before the start of the study, during the study and for 4 weeks after completion of the study - No difficult venipuncture as evidenced during the screening visit - Willing to comply to study protocol during study - Agree to take porcine / animal derived supplements (i.e. collagen) - Informed consent signed

Exclusion criteria

- Allergy or intolerance to collagen or collagen hydrolysates - Serum total cholesterol >= 8.0 mmol/L - Serum triacylglycerol >= 4.5 mmol/L - Current smoker, or smoking cessation <12 months - Diabetic patients - Familial hypercholesterolemia - Abuse of drugs - More than 4 alcoholic consumptions per day or 21 per week - Unstable body weight (weight gain or loss > 3 kg in the past three months) - Use medication known to treat blood pressure, lipid or glucose metabolism - Use of an investigational product in another biomedical intervention within the previous month - Severe medical conditions that might interfere with the study, such as epilepsy, asthma, kidney failure or renal insufficiency, chronic obstructive pulmonary disease, inflammatory bowel diseases, auto inflammatory diseases and rheumatoid arthritis - Active cardiovascular disease like congestive heart failure or cardiovascular event, such as an acute myocardial infarction or cerebrovascular accident - Not willing to give up being a blood donor from 8 weeks before the start of the study, during the study or for 4 weeks after completion of the study - Not or difficult to venipuncture as evidenced during the screening visit - Use of

over-the-counter and prescribed medication or supplements, which may interfere with study measurements to be judged by the principal investigator; - Use of oral antibiotics in 40 days or less prior to the start of the study; - Blood donation in the past 3 months before the start of the study - Not willing to comply to study protocol during study or sign informed consent - Not willing to consume the collagen hydrolysate because this is from animal origin

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-05-2021
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	08-05-2020
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	26-04-2022
Application type:	Amendment

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	24-07-2023
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	ID
CCMO	NL72922.068.20