A proof of concept study to demonstrate a cholesterol-lowering benefit of oven-dried Rhodospirillum rubrum

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48754

Source
ToetsingOnline

Brief title
Rhodospirillum rubrum and cholesterol

Condition

- Other condition

Synonym
cholesterol metabolism, risk factors for cardiovascular diseases

Health condition

cholesterol metabolisme

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: EzCol BV

Intervention

Keyword: LDL cholesterol, Proof of concept study, Rhodospirillum rubrum

Outcome measures

Primary outcome

The primary endpoint is the change in serum LDL cholesterol concentrations.

Secondary outcome

Secondary study parameters are:

- Additional CVD risk markers like circulating concentrations of total

cholesterol, triacylglycerol, HDL cholesterol, glucose and hsCRP as well as

systolic and diastolic blood pressure

- Markers for liver (ALAT, ASAT yGT), kidney (creatinin) and heart function

(NT-ProBNP, vWF, c-Troponin T).

Study description

Background summary

Cardiovascular diseases are still the leading cause of morbidity and mortality in the modern Western societies. Dietary interventions that aim to lower serum LDL cholesterol concentrations are important, since a high LDL cholesterol is causally related to cardiovascular risk. A reduction in serum LDL cholesterol concentrations by 10% lowers future CVD risk by 20%.

Study objective

The primary objective of the proposed study is to examine for the first time the LDL cholesterol lowering effect of oven-dried Rhodospirillum rubrum in humans. Secondary objectives are to investigate the effects on other CVD risk

parameters: total cholesterol, triacylglycerol, HDL-C, glucose and blood pressure. Finally, we will monitor safety parameters by weekly measurements of a panel of endpoints consisting of markers for liver (ALAT, ASAT, *GT), and kidney (creatinin) function as well as heart function (NT-ProBNP, vWF, c-Troponin T).

Study design

The proposed study is a 4-weeks randomized, double-blind placebo-controlled trial with a parallel design using 3 doses oven-dried Rhodospirillum rubrum.

Intervention

During the intervention period of 4 weeks, men will receive either placebo or capsules containing 0.25 gr, 0.5 gr or 1.0 gr oven-dried Rhodospirillum rubrum per day.

Study burden and risks

Men will be screened to determine eligibility during a visit of 15 minutes. During this screening visit, 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 9 separate blood-sampling moments. No direct health benefit for the study participants is expected, besides the potential reduction in serum LDL cholesterol concentrations. Based on animal experiments, investigational products are safe and suitable for human consumption. Potential effects on heart function as seen by thousands fold higher doses in animal studies will be monitored. In total during the entire study 230 mL blood will be sampled (one screening of 5 mL, and nine times 25 mL fasting blood, during the study). Some study subjects may report pain during venipuncture. In addition, part of the study population will be asked to complete a food frequency questionnaire twice. 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 4 hours, excluding travel time.

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

- Aged between 18-75 years;
- Men;
- Minimum 80 kg body weight;
- Serum total cholesterol between 5.0 - 8.0 mmol/L;
- Serum triglycerides concentrations below 4.5 mmol/L;
- No signs of liver and/or kidney dysfunction;
- No diabetic patients;
- No familial hypercholesterolemia;
- No abuse of drugs;
- Not more than 4 alcohol consumptions 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 trial within the previous 1-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;
- 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;

- Informed consent signed.

Exclusion criteria

- Serum total cholesterol < 5.0 mmol/L or * 8.0 mmol/L;
- Serum triglyceride concentrations * 4.5 mmol/L;
- Signs of liver and/or kidney dysfunction;
- 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 within another biomedical intervention trial within the previous 1-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.

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):	14-06-2018
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	27-11-2017
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	07-08-2018
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
Other	Na goedkeuring van de METC wordt het protocol in ClinicalTrials.gov geregistreerd
CCMO	NL62698.068.17