The effect of a single dose of Lycium Barbarum on postprandial energy expenditure in healthy overweight men

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

Summary

ID

NL-OMON43393

Source
ToetsingOnline

Brief title
Goji berries and energy expenditure

Condition

- Other condition

Synonym
Energy metabolism, risk factors for cardiovascular diseases

Health condition

Metabolisme

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Energy expenditure, Human intervention study, Lycium Barbarum, Postprandial metabolism

Outcome measures

Primary outcome

The primary outcome of this study will be postprandial energy expenditure

measured with the ventilated hood system.

Secondary outcome

Secondary study parameters are postprandial lipid and glucose oxidation,

metabolic flexibility (determined as changes in the respiratory quotient),

postprandial concentrations of triglycerides, apolipoprotein B48, free fatty

acids, insulin, C-peptide, glucose, IL-6, TNFa, postprandial leukocyte count

and differentiation and in vitro cytokine production.

Study description

Background summary

Effects of foods or food substances on energy expenditure are of particular interest, because of the increasing prevalence of obesity and its consequent metabolic diseases like type II diabetes and fatty liver disease, all risk factors for the development of CVDs. Recently, the Goji berry (Lycium Barbarum, wolfberry) was introduced into the Western diet. L. Barbarum originates from Asia, where it is used to improve the health of several organs. Although L. Barbarum is promoted as a super food with many beneficial effects, consistent scientific evidence for these effects is lacking. In one study, it was found that short-term intake of L. Barbarum polysaccharides - equal to 150 g of fresh berries - increased postprandial oxygen consumption. This indicates that L.

Barbarum might exert beneficial effects on energy expenditure. Furthermore, long-term intervention trials have shown beneficial effects of L. Barbarum on lipid and glucose metabolism in mice and type II diabetic patients and on inflammatory status in healthy elderly. Altogether, L. Barbarum has the potential to be used as a functional food to increase metabolic health, but detailed information on the postprandial effects of L. Barbarum is missing.

Study objective

The primary objective of this study is to investigate the effect of a single dose of L. Barbarum on postprandial energy expenditure. Secondary objectives are to investigate the effect of a single dose of L. Barbarum on postprandial lipid and carbohydrate oxidation and metabolic flexibility, on postprandial lipid and glucose metabolism and on inflammatory markers.

Study design

This is a double blind, randomized, placebo-controlled intervention trial with two test days separated by a washout period of at least 1 week.

Intervention

All subjects will receive a mixed meal including 25 grams of dried L. Barbarum as the intervention product and a matched mixed meal without L. Barbarum as the placebo product. The meals will be matched for energy content and macronutrient composition.

Study burden and risks

Subjects will be screened for eligibility before the start of the study during a screening visit of approximately 20 minutes. During the screening visit, blood samples (5.5 ml) will be drawn using vena puncture for serum total cholesterol, TAG, HDL-C and plasma glucose analysis and body weight and height will be measured. The study consists of two test days separated by a washout period of at least one week. Each test day lasts approximately 5,5 hours. On these test days, a postprandial test will be performed. Subjects will visit the university after an overnight fast of at least 12 hours. During the postprandial test, subjects are not allowed to consume any foods or drinks except for water. Nine blood samples will be taken during the test with a total volume of 107 ml per test day using an intravenous cannula. Furthermore, indirect calorimetry will be measured at baseline and between T = 0 min * T = 140 min, T = 160 min * T = 200 min and T = 220 * 260 min after meal intake. Subjects will be asked to complete a food frequency questionnaire at home and keep record of changes in health and alcohol use in a diary. Blood sampling might cause bruising or hematoma. Indirect calorimetry might evoke claustrophobic reactions, but there are no physical risks involved. Total time

investment for subjects is approximately 11 hours, excluding traveling time. L. Barbarum is commercially available and we therefore do not foresee any risks related to the consumption of this food product.

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

- Male gender
- Aged between 18 and 65 years
- BMI between 25-30 kg/m2
- Non-smoking
- Normal triacylglycerol levels (<2.2 mmol/L)
- No hyperglycaemia or hypercholesterolemia (fasting glucose < 7.0 mmol/L and total cholesterol < 8.0 mmol/L)

- Signed informed consent

Exclusion criteria

- Use of anticoagulant medication
- Any medical condition that can interfere with the study judged by the principal investigator:
- Usage of any kind of medication or medically prescribed diet that can interfere with the results of the study, judged by the principal investigator
- Usage of antibiotics in the three weeks prior to the screening or during the study
- Usage of food supplements or plant stanol/sterol enriched products in the three weeks prior to the screening and during the study
- Indication of treatment according to the Standard for Cardiovascular risk management by the Dutch General Practitioners community
- Participation in any other biomedical trial one month prior to the screening visit
- Having donated > 150 ml blood within 1 month prior to the screening visit, planning to donate blood during the study or within one month after finishing the study
- Consumption > 14 glasses alcohol per week
- Reported intense sporting activities > 10 hours per week
- Abuse of drugs

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-04-2016
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	30-03-2016
Application type:	First submission
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 het ClinicalTrials.gov geregistreerd
CCMO	NL55654.068.15