Acute effects of coffee and major coffee components on glucagon-like peptide 1 response and glucose tolerance in humans

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To test whether chlorogenic acid and trigonelline ingestion acutely reduce postprandial glucose concentrations in humans. In addition, we will examine whether effects on glucagon-like peptide 1 secretion and dipeptidyl peptidase IV inhibition are...

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

Summary

ID

NL-OMON31301

Source
ToetsingOnline

Brief title
Coffee consumption and glucose tolerance in humans

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes, impaired glucose tolerance

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Diabetes Fonds Nederland

Intervention

Keyword: chlorogenic acid, coffee, glucose tolerance, trigonelline

Outcome measures

Primary outcome

Concentrations of glucose, insulin, glucagon-like peptide 1 secretion, and the

activity of dipeptidyl peptidase IV will be measured during 2 hours following

an oral glucose tolerance test.

Secondary outcome

N.A.

Study description

Background summary

High coffee consumption is associated with a lower risk of type 2 diabetes in prospective cohort studies in the U.S., Europe and Japan. Similar associations are observed for caffeinated and decaffeinated coffee, suggesting that coffee components other than caffeine have beneficial effects on glucose homeostasis. Chlorogenic acid and trigonelline are major components in coffee and may be partly responsible for improved glucose tolerance following coffee consumption. Administration of these substances decreased glucose levels in animal studies, but there are no studies in humans.

Study objective

To test whether chlorogenic acid and trigonelline ingestion acutely reduce postprandial glucose concentrations in humans. In addition, we will examine whether effects on glucagon-like peptide 1 secretion and dipeptidyl peptidase IV inhibition are responsible for beneficial effects on glucose tolerance.

Study design

Double-blind, placebo controlled, cross-over trial

Intervention

Each subject will be randomly assigned to one out of 24 treatment orders.
The four interventions are:
1) 0.5 L decaffeinated coffee (2 large cups)
2) ~1,000 mg chlorogenic acid (comparable to 1.0-2.0 L of strong coffee)
3) ~500 mg trigonelline (comparable to 0.5-1.0 L of strong coffee)
4) ~1,000 mg mannitol (placebo).

Study burden and risks

The procedures the participants will undergo:
- Single intake of supplements of dietary components. Subjects in this study will be regular consumers of coffee and therefore the subjects consume these compounds on a daily basis.
- Blood withdrawal through a catheter in the antecubital vein. This is a very common procedure and its risk is considered low.
Therefore, the proposed study does not impose a large burden on the participants. There will not be any direct medical benefits for the participants. Eventually, the identification of coffee components with beneficial effects on glucose metabolism could lead to the development or selection of coffee types, or other foods with high levels of these substances which contribute to the prevention of type 2 diabetes.

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

- Apparently healthy males as assessed by the questionnaires during the pre-study visit, and the results of the pre-study clinical laboratory tests and urinalysis
- Age at screening: 18 years and above
- Body mass index (BMI) between 25.0 and 35.0 kg/m2
- Regular coffee consumer (1 cup per day or more)
- Willing to restrict coffee consumption during the study to max. 1 cup per day
- Voluntary participation
- Willing not to be blood or plasmaferese donor from 4 weeks before the start of the study until the end of study

Exclusion criteria

- Women
- Smokers
- Subjects with diabetes will be excluded (fasting blood glucose >= 7.0 mmol/l or physician-diagnosis of diabetes)
- Blood sampling is considered too difficult (assessed during pre-study screening)
- Any chronic or acute disease (e.g. diabetes, renal disease, inflammation, cardiovascular disease). Therefore the medical questionnaire will be evaluated by a doctor from the research team.
- Hypertension criteria for moderate hypertension WHO 2003: systolic > 140 mmHg or diastolic > 90 mmHg
- Medical history or surgical events known to interfere with the study
- Alcohol consumption > 28 consumptions per week
- Self reported weight loss or gain > 2 kg in the month prior to screening
- Any special diet (prescribed, slimming, macrobiotic or vegan). Sole exclusion of meat and fish from an otherwise *normal* western diet is allowed

- Participation in any other trial up to 3 months before and during this study
- Use of medication known to interfere with the study outcome e.g.: Medication interfering with digestion or glucose metabolism, such as corticosteroids and beta-blockers
- Exercising more than 4 hours vigorously per regular week

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-08-2007
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL17481.029.07