Effects of long-term resveratrol supplementation on metabolic health

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

Summary

ID

NL-OMON44710

Source
ToetsingOnline

Brief title
long-term resveratrol and metabolism

Condition

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

Synonym
obesitas and sugar disease

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Nederlands Diabetes Fonds

Intervention

Keyword: Glucose Tolerance, Metabolism, Resveratrol, Type 2 diabetes

Outcome measures

Primary outcome

The most important study parameters are differences in: glucose tolerance,

resting energy expenditure, intra-hepatic lipid content, body composition and

blood plasma values

Secondary outcome

Secundairy outcome parameters are changes in: blood pressure, muscle strenght,

quality of sleep and quality of life

Study description

Background summary

There is now a general consensus that the combination of excessive energy intake and a low capacity to oxidize fat will lead to muscular fat accumulation and insulin resistance. It is known for many years that physical activity and diet therapy are the most powerful treatment to combat obesity and insulin resistance, but it is also known that it is difficult to get people to exercise and follow diets. A major breakthrough in this field has come from the nutrition field, with the finding that resveratrol, a natural polyphenolic compound, could serve as an *caloric restriction mimetic*, as a recent study of S. Timmers et al. in Cell metabolims (2011) showed that resveratrol mimicked the effect of caloric restriction in healthy obese man (lowering liver fat accumulation and increasing fat oxidation, thereby improving metabolic health in these subjects). These findings were similar to those found earlier in animal studies, where it was found that resveratrol protected mice from many detrimental effects of diet-induced obesity. The purpose of the current study is to investigate if resveratrol has the same beneficial effects if resveratrol is given for a longer period (6 months) in people with overweight/obesity. This information can be used to develop new preventive strategies for type 2 diabetes. Therefore we will investigate the effects of long-term (6 months) resveratrol supplementation on insulin sensitivity (estimated by Matsuda Index). In addition we will investigate effects of resveratrol on other

(metabolic) parameters such as: body composition, intra-hepatic lipid accumulation, resting energy expenditure, blood pressure, plasma values, muscle strenght and quality of life.

Study objective

The purpose of the study is to investigate wether long-term resveratrol supplementation (6 months) leads to improved insulin sensitivity (estimated by Matsuda Index) in people with overweight/obesity. In addition we will investigate effects of resveratrol on other (metabolic) parameters such as: body composition, intra-hepatic lipid accumulation, resting energy expenditure, blood pressure, plasma values, muscle strenght and quality of life.

Study design

Double blind, randomised, parallel design, clinical trial in which resveratrol supplementation will be compared to placebo

Intervention

Particicpants will take 2 times a day a capsule of resversatrol (75 mg) or placebo: 1 during lunch and 1 during the evening meal for a period of 6 months.

Study burden and risks

Before the start of the intervention potential paricipants are screened to determine wether they are eligible for participation in the study. This screening entails filling in a medical history questionnaire, drawing of a fasting blood sample and determination of body weight (total duration: 1 hour). During the 6-month intervention period the participants will visit the university 9 times (Month 0 2x, Maand 1, 2, 3, 4, 5 and Month 6 2x). During these visits to the university a fasting blood sample will be drawn and body weight and blood pressure are checked. During the visits of Month 0 and Month 6 the following measurements will be performed: MRS scan (for determination of intra-hepatic lipid content), DEXA scan, OGTT (2 times before and after 6 months), indirect calorimetri, questionnaires about food intake and habitual physical activity, queastionnaires about quality of sleep and quality of life and muscle stranght (timed chair stand test, 6-minute walk test and Biodex). Participation in the entire study costs the participants about 25 hours (including the screening).

The following risks are present:
- The blood drawings can cause a bruise and swelling
- The radiation of the DEXA scan is very low and because of this low dose the risks on the long-term are negligible

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

* Men aged 40-70 years and postmenopausal women aged 50-70 years
* BMI: 27-35 kg/m2
* Stable dietary habits: no weight gain or loss > 5kg in the last three months
* Willingness to limit consumption of resveratrol-containing food products and willingness to refrain from using resveratrol containing supplements
* Subjects will only be included when the dependent medical doctor of this study approves participation after evaluating data obtained during screening

Exclusion criteria

* Uncontrolled hypertension

* HbA1c > 6.5%
* Previously diagnosed with type 2 diabetes
* Medication use known to interfere with glucose homeostasis/metabolism
* Current alcohol consumption > 20 grams alcohol/day
* Subjects who do not want to be informed about unexpected medical findings during the screening /study, or do not wish that their physician is informed, cannot participate in the study.
* Participation in another biomedical study within 1 month before the start of the intervention
* Any condition, disease or abnormal laboratory test result that, in the opinion of the Investigator, would interfere with the study outcome, affect trial participation or put the subject at undue risk

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-04-2016
Enrollment:	58
Type:	Actual

Ethics review

Approved WMO

Date:	16-03-2016
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
CCMO	NL53016.068.15
Other	not yet assigned

Study results

Date completed: 01-04-2019

Actual enrolment: 42

Summary results
Trial is onging in other countries