The effect of Momordica charantia supplementation on blood glucose levels

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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-OMON48458

Source
ToetsingOnline

Brief title
Bitter-sweet

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
blood glucose, glucose tolerance

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Europese Unie (EFRO);provincie Zuid Holland en het ministerie van Economische Zaken.

Intervention

Keyword: blood glucose, glucose tolerance, Momordica charantia

Outcome measures

Primary outcome

fasting levels of plasma glucose and 2hour plasma glucose after a 75-gram OGTT.

Secondary outcome

HbA1c, fructosamine, insulin (fasting and in response to a 75-OGTT). From the

fasting glucose and insulin values we will calculate HOMA-IR score. We will

also measure glucose responses during a three day controlled dietary period.

Study description

Background summary

Bitter gourd (BG) (Momordica charantia), is a highly nutritive vegetable from the cucumber family. It*s fruit (but also other parts of the plant) is widely consumed around the world and it is particularly known for its bitter taste and distinct warty exterior and an oblong shape. BG is proposed to possess a wide range of medicinal properties. However, most of these claimed health effects lack solid scientific evidence, or scientific evidence is based on results of in vitro or animal models. However, promising potential health effects of BG are described for its lowering potential of blood glucose. Therefore BG has great potential to be used as an ingredient or dietary supplement for diabetics and pre-diabetic patients.

Study objective

We aim to assess the impact of 4-week BG supplementation on blood glucose levels and glucose tolerance in subjects with an impaired fasting glucose or with an impaired glucose tolerance. In addition we will evaluate how BG supplements modulate glucose response curves during meal intake. We will do this in a dietary controlled setting and via continues blood glucose measurements.

Study design

The study is a randomised, cross-over, double blind, controlled trial in which study participants will receive two 4-week interventions with a washout period of 4 weeks between interventions. Study subjects will visit our research facility before and after each intervention period for a test day. In the third intervention week we will provide a 3-day controlled diet and we will monitor glucose responses via a continuous glucose monitoring device.

Intervention

4-week intervention with 2.4g/d dried bitter-gourd supplements and a reference intervention with 2.4g/d dried cucumber supplements.

Study burden and risks

There are minor risks for the participants of this study. There are no direct benefits for the participants. The total amount of blood collected during the study is within the accaptable range and therefore not expected to cause any problems. Blood collection via a catheter may cause some discomfort and a bruise. Study subjects that will participate in the study will invest approximately 31 hours during the trial and need to visit the research facility on 14 occasions. All intervention products (BG and cucumber) are available in supermarkets. We will provide a daily dose of 2.4g dried BG (equivalent to approximately 100g fresh BG).

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

age 50-75yrs
BMI >25 kg/m2
Having veins suitable for blood sampling via a catheter (judged by study nurse/medical doctor)
Having one or more of the following criteria:
o HbA1c >5.7%
o fasting glucose >5.6mmol/L
o two-hour glucose levels >7.8 mmol/L on the 75-g oral glucose tolerance test .

Exclusion criteria

* History of gastro-intestinal surgery or having (serious) gastro-intestinal complaints
* History of liver dysfunction (cirrhosis, hepatitis) or liver surgery
* Kidney dysfunction (self-reported)
* Use of medication/supplements that may influence the study results, such as medicines known to interfere with glucose homeostasis (judged by medical doctor)
* Anaemia (Hb values <7.5 for women and <8.5 for men)
* Reported slimming, medically prescribed or other extreme diets
* Reported weight loss or weight gain of > 5 kg in the month prior to pre-study screening
* Not willing to give up blood donation during the study
* Current smokers
* Alcohol intake *4 glasses of alcoholic beverages per day
* Abuse of illicit drugs
* Food allergies for products that we use in the study
* Participation in another clinical trial at the same time
* Being an employee of the Food, Health & Consumer Research group of Wageningen Food & Biobased Research or dept. human nutrition and health of Wageningen University.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-09-2019
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	21-08-2019
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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
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