The effect of long-term Momordica Charantia supplementation on blood glucose levels

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We aim to assess the impact of 12-week BG supplementation on blood glucose levels in subjects with impaired fasting glucose levels.

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

Summary

ID

NL-OMON51413

Source
ToetsingOnline

Brief title
Bitter-Sweet 2 study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
blood glucose, pre-diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Food and Biobased Research
Source(s) of monetary or material Support: Provincie Zuid-Holland;EFRO en het ministerie van Economische Zaken

Intervention

Keyword: Bittergourd, Fasting blood glucose, Pre-diabetes, Supplements

Outcome measures

Primary outcome

The main study parameter is fasting levels of plasma glucose.

Secondary outcome

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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 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, in addition to lifestyle advice.

Study objective

We aim to assess the impact of 12-week BG supplementation on blood glucose levels in subjects with impaired fasting glucose levels.

Study design

The study is a parallel, double blind, controlled trial in which study participants will receive an intervention for 12 weeks. Research subjects will come to the research facility for a test day on four occasions, with an interval of 4 weeks (+/- 1 day for visits 2 and 3).

Intervention

12-week intervention with 3.6 g/d dried bitter-gourd supplements or a reference intervention with 3.6 g/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 acceptable range (8 to 12 ml per test day), and therefore not expected to cause any problems. Blood collection may cause some discomfort and a bruise. Research subjects that will participate in the study will invest approximately 31 hours during the trial and need to visit the research facility on 4 occasions. All intervention products (BG and cucumber) are based on products like available in supermarkets but then freeze dried and powdered. We will provide a daily dose of 3.6 g dried BG (equivalent to approximately 36 g 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 40-75yrs
• BMI >25 kg/m2
• Having a fasting glucose >= 5.6 mmol/L

Exclusion criteria

• Use of medication/supplements that may influence the study results, such as metformin, gliclazide, glimepiride, tolbutamide, insulin, sitagliptin (DPP4 inhibitor), liraglutide (GLP-1 agonist), acarbose, repaglinide, pioglitazone, corticosteroids (systemically) , SGLT-2 inhibitors, (judged by our research physician)
• Having a fasting glucose >11.0 mmol/L
• History of gastro-intestinal surgery or having (serious) gastro-intestinal complaints
• History of liver dysfunction (cirrhosis, hepatitis) or liver surgery
• Kidney dysfunction (self-reported)
• 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 >=14 glasses (women) or >21 glasses (men) of alcoholic beverages per week, on average
• Not pregnant or lactating
• Abuse of illicit drugs (soft- and hard 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:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	23-01-2022
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO Date:	11-01-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-03-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	het traject loopt
CCMO	NL79294.091.21

Study results