The effects of a GABA supplement versus a placebo on glucose tolerance and blood pressure in prediabetics

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To determine whether 12 weeks of GABA supplementation versus placebo supplementation can improve oral glucose tolerance in people at risk of developing type 2 diabetes and explore the effects of GABA on overall metabolic health.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49999

Source
ToetsingOnline

Brief title
GABA for Health

Condition

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

Synonym
elevated blood pressure, Type 2 diabetes

Health condition

Hypertensie

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Agrico Research,Avebe,Nunhems,Publiek private samenwerking in een TKI project met Agrico Research;Nunhems;Avebe en de Nederlandse overheid

Intervention

Keyword: bloodpressure, GABA, glucose, prediabetic

Outcome measures

Primary outcome

The main study parameter of this study is the postprandial glycaemic response during a 2 hour oral glucose tolerance test (OGTT) before and after the intervention period.

Secondary outcome

Postprandial insulin and glucagon response, plasma free fatty acids, HbA1c, glucose variability with flash glucose monitoring, blood pressure, markers of inflammation, TG and LDL and HDL cholesterol, sleep habits, depression, anxiety, GABA and glutamate plasma levels and the acute effects of GABA on postprandial glucose response and blood pressure.

Study description

Background summary

Worldwide more and more individuals can be categorized as prediabetic; the prevalence of prediabetes is expected to be higher than 470 million in 2030. About 70% of these prediabetics will eventually develop type 2 diabetes. Diabetes is for a large part preventable and in the stage of prediabetes the progression to diabetes can still be halted by lifestyle interventions. As a consequence, there is a clear need for specific foods and food components that provide additional beneficial effects. Recently identified as potential

bioactive food component is *-aminobutyric acid (GABA). GABA is widely available as a dietary supplement and it is naturally present in food products like potato, tomato and melon. Research suggests that oral GABA could function as a modulator of glucose homeostasis. GABA is able to improve insulin sensitivity and glucose tolerance in high fat diet induced diabetic rodents and to reverse chemically induced diabetes in in vivo. However, studies are needed that can determine what role GABA could play in improving glucose homeostasis in humans.

Study objective

To determine whether 12 weeks of GABA supplementation versus placebo supplementation can improve oral glucose tolerance in people at risk of developing type 2 diabetes and explore the effects of GABA on overall metabolic health.

Study design

Randomized placebo controlled double-blind parallel intervention study.

Intervention

One group receives three times daily a 500 mg GABA supplement and the other group receives three times daily a placebo.

Study burden and risks

During this study a total of 116 mL blood is drawn from the research subjects by a venous catheter. Placement of the catheter could cause bruising. An additional burden is the 4 times overnight fast. The wearing of the glucose sensor and the blood pressure monitor might also be perceived as a burden. During the measurement periods they also fill in a short food record for 5 days and 3 times a 24 hour webbased recall. They also fill in three short questionnaires about their sleeping habits, depression and anxiety. GABA is a food supplement that is present in a similar dose in our diet and is generally recognized as safe by the FDA. The GABA supplement could have minor temporary adverse events like dizziness and nausea. Taking these risks and burdens together this study will be of substantial discomfort to the research subjects. The research subjects do not directly benefit from the intervention but receive a financial compensation of ¤390,-.

Contacts

Public

Wageningen Universiteit

Stippeneng 4
Wageningen 6708PB
NL
Scientific
Wageningen Universiteit

Stippeneng 4
Wageningen 6708PB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age between 50 and 70
- BMI higher or equal to 25 kg/m2
- Impaired fasting glucose (fasting glucose * 5.6 and * 6.9 mmol/L) or/and
- Impaired glucose tolerance (glucose levels * 7.8 and * 11.1 mmol/L, 2-hours after an OGTT or/and glucose levels *8.6 mmol/L, 1-hour after an OGTT)

Exclusion criteria

- Has been diagnosed with diabetes
- Having other conditions, like liver, pancreatic, cardiovascular, gastro-intestinal or endocrine diseases, that could influence the study results
- Use of medications or supplements that could influence the study results
- Sensitive to medical skin adhesives
- More than 5kg weight change in the past 12 weeks
- Excessive alcohol consumption (>21 glasses/week for men and >14 glasses/week

for women on average)
- Being an employee of Wageningen University, division Human Nutrition and Health
- Currently a research subject in other research

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-11-2020
Enrollment:	52
Type:	Actual

Ethics review

Approved WMO

Date:	01-09-2020
Application type:	First submission
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
ClinicalTrials.gov	NCT04303468
CCMO	NL73194.081.20