Plasmakinetics of gamma-aminobutyric acid from tomatoes as compared to a supplement, after a single oral administration in healthy young men

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This study aims to establish a plasmakinetic profile of GABA from tomatoes in healthy men and compare it to the kinetic profile of GABA from a supplement. In addition, the effects of glutamate (precursor of GABA) on the plasma-time curves of GABA…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48303

Source
ToetsingOnline

Brief title
Relative oral bio-availability of GABA from tomatoes

Condition

- Other condition

Synonym
plasmakinetics of GABA

Health condition

Voedingsonderzoek

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: Bio-availability, GABA, Glutamate, Tomato

Outcome measures

Primary outcome

The main study outcome is the plasma-time curve of GABA. This will be evaluated

using descriptive kinetics: maximum peak height (Cmax), time-to-peak (Tmax),

and area-under-the-curve (AUC).

Secondary outcome

- To evaluate the effects of an oral GABA dose and tomatoes on the plasma

concentrations of glutamate in healthy men.

- To evaluate the effects of a single oral glutamate dose on the plasma

concentrations of GABA and compare this to the plasma concentrations of GABA

after the intake of a tomatoes.

Study description

Background summary

Next to its role as a neurotransmitter, GABA has been identified as potential bioactive food component, abundantly present in for example certain varieties of potato and tomato. Animal studies show beneficial effects of orally administered GABA in relation to diabetes development and hypertension. Since tomatoes and potatoes are frequently consumed by the Dutch (and other

nationalities), these products could potentially be used to substantially increase the GABA intake. However, this depends on the assumption that GABA is effectively absorbed from the food matrix. We expect that the food matrix changes the bio-accessibility and bio-availability of GABA; a food matrix can entrap nutrients or protect them from degradation for example. From literature it is known that GABA is rapidly absorbed from a supplement but the bioavailability of GABA from a food matrix has not previously been investigated.

Study objective

This study aims to establish a plasmakinetic profile of GABA from tomatoes in healthy men and compare it to the kinetic profile of GABA from a supplement. In addition, the effects of glutamate (precursor of GABA) on the plasma-time curves of GABA will be studied.

Study design

This study has a placebo controlled randomized four-way crossover design, with four test days with a minimum of 1 week washout in between.

Intervention

On a test day the research subjects will consume either tomatoes with 1 gram of GABA, a dose of 1 gram GABA supplement dissolved in a maximum of 1 litre water, a glutamate supplement with a maximum dose of 8 grams, dissolved in a maximum of 1 litre water or a maximum of 1 litre water. The dosage of glutamate and the amount of water are adjusted to the amount of glutamate in the pureed tomatoes and the volume of the pureed tomatoes.

Study burden and risks

GABA and glutamate are naturally present in our diet and are generally recognised as safe for use as a food ingredient by the FDA. In human intervention studies, oral ingestion of GABA or glutamate does not lead to severe adverse events. Some temporary minor adverse events, like nausea, did occur. Therefore, the research subjects in this study might also experience these temporary effects. In addition, the research subjects are required to visit the university a total of 14 times and during the blood sampling they are required to remain at the research facilities. On the test days the research subjects arrive in a fasted state and remain fasted until 4 hours after intake of the test product. The placement of venous catheters and blood sampling will also lead to mild discomfort. Research subjects do not directly benefit from the intervention but contribute to scientific research and receive a financial compensation of ¤470,- when completing the whole study.

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

- BMI between 18.5 and 25 kg/m2
- Age is between 18 and 28 years
- Good general health
- Male
- Veins suitable for blood sampling
- Able to speak Dutch

Exclusion criteria

- Is currently suffering from a disease including mental disorders
- Has had any gastrointestinal condition/disease within the 3 months prior to

the intervention
- Haemoglobin (Hb) level < 8.5 mmol/L
- Has used medication in the two months before and/or during the intervention.
Occasional use of NSAIDs or paracetamol (- Reported weight loss or weight gain of > 2 kg in the month prior to the
intervention
- Use of dietary supplements, 3 weeks before-, or during the intervention.
- Allergic to products that are provided as part of the standardised diet
- Following a specific diet (e.g. vegetarian, gluten free)
- Allergic to tomatoes
- (History of) drug abuse, in this case meaning >1 x per month use of
recreational drugs
- Smoking
- Alcohol consumption of >10 standardised glasses per week.
- Recent or planned blood donation (<3 month prior to first study day or during intervention)
- Personnel of Wageningen University, department of Human Nutrition and Health,
- Currently participating in other research or was participating in another
study within 1 month of the intervention or within 3 months if invasive
procedures were used.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-04-2019
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO Date:	23-09-2019
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
CCMO	NL67923.081.19
Other	NL7808