Relative oral bioavailability of GABA from tomatoes

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25547

Source
NTR

Brief title
GO-Tomaat

Health condition

n.a. healthy research subjects

Sponsors and support

Primary sponsor: Wageningen University and Research
Source(s) of monetary or material Support: TKI-project with Agrico research, Nunhems and Avebe

Intervention

Outcome measures

Primary outcome

The main study parameter is the plasma-time curve of GABA after intake of a GABA supplement and tomatoes. This will be studied using descriptive kinetics (maximum peak height (Cmax), time-to-peak (Tmax), Half-life (T1/2) and area-under-the-curve (AUC)).

Secondary outcome

Secondary study parameters are:
- The plasma-time curves of glutamate in response to a glutamate supplement and tomatoes.
- The plasma-time curves of GABA in response to a glutamate supplement in comparison to the plasma time-curves of GABA after tomato intake.

Study description

Background summary

Rationale: Next to its role as a neurotransmitter, GABA has been identified as potential bioactive food component. It is 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 a 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.

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.

Study population: 12 subjects, all healthy young men.

Intervention: On a test day, the research subjects will consume either tomatoes with 1 gram of GABA, a dose of 1 gram GABA supplement, a glutamate supplement with a maximum dose of 8 grams or a placebo.

Main study parameters/endpoints: 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).
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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.

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. We hypothesize that a food matrix will affect the plasmakinetics of GABA.

Study design

For the study, research subjects will visit the university on four test days separated by a wash out period of one week.

Intervention

Tomatoes, GABA supplement, Glutamate supplement, Placebo

Contacts

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Tessa de Bie

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Eligibility criteria

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 (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
- Unwilling to consume the products that are part of the standardised diet
- 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.
- Not able to refrain from alcohol consumption 2 days before each test day
- 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:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-11-2019
Enrollment:	12
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
n.a.

Ethics review

Positive opinion

Date:	18-06-2019
Application type:	First submission

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
NTR-new	NL7808
Other	METC-WU : METC-nr 19/13

Study results

Summary results
n.a.