Effects of sub chronic oral tryptophan administrations on stress-induced mood and eating behaviour in healthy female volunteers differing in the 5-HTTLPR genotype

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1) Examining actual changes in food intake and food preference for different foods following psychosocial laboratory-induced stress;2) Examining the effect of multiple (instead of single) dietary TRP administration on acute stress-induced (negative...

Ethical review Approved WMO

Status Recruitment stopped

Health condition type Appetite and general nutritional disorders

Study type Interventional

Summary

ID

NL-OMON37605

Source

ToetsingOnline

Brief title

5-HTTLPR genotype, sub chronic TRP, stress and emotional eating

Condition

Appetite and general nutritional disorders

Synonym

emotional eating, stress-induced eating

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: 5-HTTLPR genotype, Emotional eating, Stress, Tryptophan

Outcome measures

Primary outcome

the main study parameters are changes in mood, state-anxiety, eating behaviour (anticipated preference, appetite, and actual intake and macronutrient selection) and salivary cortisol, both before and after TRP or PLC treatment and before and after stress-induction. Blood samples will be taken twice on the first, and twice on the final day of treatment, to measure dietary (TRP) induced changes in plasma amino acids (TRP/LNAA ratio).

Secondary outcome

N/A

Study description

Background summary

Serotonin is involved in both the regulation of mood as well as the control of energy intake. Individuals with different 5-HTTLPR genotypes have dissimilar serotonergic neurotransmission; and the s-allele of the 5-HTTLPR has been shown to predispose for a serotonergic vulnerable system, and hence increased susceptibility to stress, stress-related depression and disinhibited eating behaviour. This would suggest different emotional (mood) and behavioural (eating) responses after acute stress exposure depending on genotype. These stress-induced negative effects can be prevented by augmentation of brain 5-HT through administration of dietary tryptophan (TRP), the sole precursor of 5-HT. Previous investigations have shown significant 5-HTTLPR genotype-related differences in blood plasma TRP levels and brain TRP uptake after acute, oral

TRP administration, but the effects of chronic TRP supplementation are still unknown. In order to develop a better understanding of serotonergic functioning in 5-HTTLPR genotypes, and the association with stress-sensitivity and the effects on mood and eating, the present aim is to examine the effect of stress on anticipated appetite and food preference, on actual food intake and preference, as well as the effect of multiple (sub chronic) daily dietary TRP administration, and the functional role of allelic variation of the 5-HTTLRP therein.

Study objective

- 1) Examining actual changes in food intake and food preference for different foods following psychosocial laboratory-induced stress;
- 2) Examining the effect of multiple (instead of single) dietary TRP administration on acute stress-induced (negative) affect and eating behaviour;
- 3) Examining whether individuals with different versions of the 5-HTTLPR genotype and different levels of cognitive stress sensitivity (high vs. low Neuroticism) react differentially to stress and stress induced changes in mood and eating behaviour;
- 4) Examining whether individuals with different versions of the 5-HTTLPR genotype and different levels of cognitive stress sensitivity (high vs. low Neuroticism) react differentially to the (beneficial) effects of dietary TRP augmentation with regard to stress-related changes in mood and eating behaviour.

Study design

This study will be conducted in accordance to a between-subjects randomized placebo-controlled design.

Intervention

Half of participants will be provided with TRP-rich drinks (100 ml containing 1.0g of TRP, three times a day), and half will be provided with placebo (PLC) drinks (100 ml, three times a day) for seven consecutive days. Before start of the treatment phase (baseline measure), as well as after seven treatment days (TRP or PLC), all subjects will be exposed to a laboratory stress-induction procedure.

Study burden and risks

The drinks (TRP and placebo) originate from natural food sources from which no adverse effects are reported. The stress-induction tasks (a mental arithmetic task and a public speaking task) have been used frequently in several studies and have been proven to be safe research paradigms, which are well tolerated and do not induce any psychological negative after-effects or damage. There are

no indications that salivary sampling (5 times each test day), blood sampling (4 times in total), or mood assessments (3 times each test day) elicit any intolerant discomfort or meaningful affective changes.

Contacts

Public

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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 between 18 and 30 years
Body Mass Index (BMI) between 20 and 25 kg/m2
Beck Depression Inventory score (BDI; Beck et al. 1961) below 11
Subjects willing and able to give written informed consent and to understand, to participate and to comply with the research project requirements.

Exclusion criteria

Chronic and/or current illness

Personal or family history of psychiatric illness

Prescription medication use

Experience with panic attack/hyperventilation attack

Excessive use of alcohol (>1 units per day, 1 unit: 300ml beer, 1 glass of wine or 1 measure of spirit), coffee and/or drugs

Smoking

Any use of alcohol or drugs during the experiment, starting 2 days before the experimental session until the end of the experiment

Pregnancy and breast feeding

(also see section 4.3 of research protocol)

Study design

Design

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Double blinded (masking used)

Control: Placebo

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 26-03-2012

Enrollment: 120

Type: Actual

Ethics review

Approved WMO

Date: 16-04-2012

Application type: Amendment

Review commission: METC academisch ziekenhuis Maastricht/Universiteit

Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date: 23-04-2012

Application type: First submission

Review commission: METC academisch ziekenhuis Maastricht/Universiteit

Maastricht, METC azM/UM (Maastricht)

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 NL39138.068.11