

Neuro-cognitive effects of tyrosine supplementation in older adults

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

Summary

ID

NL-OMON42026

Source

ToetsingOnline

Brief title

Tyrosine and the aging brain

Condition

- Other condition

Synonym

healthy aging, old age

Health condition

gezonde veroudering

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen

Source(s) of monetary or material Support: Europees fonds voor regionale ontwikkeling (EFRO; EU en provincie)

Intervention

Keyword: aging, cognitive control, prefrontal cortex, tyrosine

Outcome measures

Primary outcome

We will assess the effect of the intervention on BOLD signal measured with functional magnetic resonance imaging (fMRI) and response times and accuracy on the computerized tasks during fMRI.

Secondary outcome

Secondarily, effects on paper and pencil neuropsychological tasks will be assessed. Also, intervention effects on subjective measurements (e.g. self-report questionnaires, visual analogue scales), on catecholamine and serotonin metabolites (MVA - metanefrine, HVA - normetinefrine, HVA - 3-MT and 5-HIAA) in urine samples, and on physiological recordings (blood pressure, heart rate) will be measured.

Study description

Background summary

In this study, we aim to investigate the neurocognitive mechanism of the food supplement tyrosine in healthy older adults. The aging brain has a shortage of dopamine, especially in the prefrontal cortex. The amino acid tyrosine, a precursor of dopamine, has been shown to reduce cognitive impairments in young adults during environmental stress such as cold induction, acoustic noise or a demanding task. The suggested mechanism behind this effect is that stress

depletes dopamine and noradrenaline in the brain, which can be repleted by tyrosine. Tyrosine supplementation could possibly also replete dopamine levels in the aging brain, thereby improving prefrontal cortex functioning and associated cognition.

Study objective

We aim to assess the neurocognitive mechanisms of tyrosine supplementation in older adults during different forms of cognitive control depending on the prefrontal cortex: working memory, reactive and proactive response inhibition, and effort discounting.

Study design

We will use a double blind, counterbalanced, placebo-controlled, within-subject study design. Subjects will be tested twice using fMRI, once on placebo and once on tyrosine supplementation, and will be pre-screened during an intake session.

Intervention

Subjects will receive either 150 mg/kg body weight tyrosine or 50 mg/kg body weight Fantomalt diet carbohydrate powder mixed with 100 mg/kg cornstarch (placebo condition), in both cases dissolved in 200 grams of flavoured light yoghurt on two different test days.

Study burden and risks

Subjects will come to the lab three times: once for 2,5 hour intake session and two times for 4 hour and 10 minutes testing session (of which 100 minutes tasks during fMRI). After dinner on the evening prior to and on the morning of the test session, subjects have to refrain from eating, drinking coffee or other stimulant containing drinks, as well as alcohol. Furthermore, during this time period subjects have to adhere to some simple restrictions with respect to medication and drug intake. The dosage of tyrosine can be administered safely to healthy humans without any known risk of serious adverse events.

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

Inclusion criteria (zie sectie 4.2 op pagina 12 van het protocol)

In order to be eligible to participate in this study, subjects must meet all of these criteria:

- Age: 60-75 years old
- Proficient knowledge of the Dutch language
- Right-handed
- Willing to perform tasks in the MRI scanner, to come to the centre on three occasions, consuming tyrosine or a placebo and willing to fast the night before the two test sessions.

Exclusion criteria

Exclusion criteria (see section 4.3 on page 12 of the protocol)

A potential subject who meets any of the following criteria will be excluded from participation in this study (for a checklist see F1 Intake Questionnaires and Checklists):

- Mini Mental State Examination score < 24
- HADS score > 11
- Estimated IQ < 85 (based on Nederlandse Leestest voor Volwassenen (NLV) -score)
- (History of) clinically significant psychiatric disorder
- (History of) clinically significant neurological disorder, such as brain infarct, Parkinson's Disease, chronic migraine, Diabetes Mellitus

- First degree family history of schizophrenia, bipolar disorder or major depressive disorder
- Thyroid problems and low-protein diet
- Daily use of beta blockers
- Using medication that can interfere with tyrosine's action; monoamine oxidase inhibitors and other antidepressants, sympathomimetic amines, and opioids
- General medical conditions, such as repetitive strain injury (RSI) or sensori-motor handicaps, blindness or colorblindness, as judged by the investigator
- (History of) abuse of drugs or alcohol
- Habitual smoking, i.e. more than a pack of cigarettes per week
- Participation, current or within the past twelve months, in a specific cognitive training study
- Contra-indications for MRI:
 - o Metal objects or fragments in the body that cannot be taken out
 - o Active implants in the body
 - o Using medical plasters
 - o Epilepsy
 - o Previous head surgery
 - o Claustrophobia

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	26-11-2014
Enrollment:	28
Type:	Actual

Ethics review

Approved WMO

Date: 12-11-2014

Application type: First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date: 23-02-2015

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

ID: 22035

Source: Nationaal Trial Register

Title:

In other registers

Register	ID
CCMO	NL49758.091.14
OMON	NL-OMON22035