L-Histidine depletion as a new method to examine the association of histamine and cognition in humans

Published: 28-12-2006 Last updated: 09-05-2024

The primary objective is to evaluate whether the method of histidine depletion can be used to lower histidine levels in the blood and whether it affects information processing in similar ways as can be done using antihistamines. Secondary, we will...

Ethical review Approved WMO

Status Recruitment stopped

Health condition type Other condition **Study type** Interventional

Summary

ID

NL-OMON30268

Source

ToetsingOnline

Brief title

L-Histidine depletion and cognition

Condition

• Other condition

Synonym

nvt

Health condition

geen aandoening

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

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

Intervention

Keyword: cognition, histamine, histidine depletion, information processing

Outcome measures

Primary outcome

The main endpoint is the behavioural score on the critical tracking task, a task that measures psychomotor performance. Secondary, the behavioural and event-related potential response during simple and choice reaction time tasks will be analysed. A further important parameter is the change in histidine blood plasma level after histidine depletion.

Secondary outcome

Secondary are the behavioural and brain activity scores during a verbal learning task, the Sternberg working memory scanning, and a visual oddball paradigm. These tasks enable us to assess the specificity of the effects of histidine depletion.

Study description

Background summary

A decrease in histamine availability in the brain usually affects some types of information processing, which has previously been shown when treating people with antihistamines. In this experiment, we intend to mimic these effects by investigating a novel method to experimentally lower central histamine levels by means of precursor depletion using amino acid administration.

Study objective

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The primary objective is to evaluate whether the method of histidine depletion can be used to lower histidine levels in the blood and whether it affects information processing in similar ways as can be done using antihistamines. Secondary, we will assess whether histidine depletion affects information processing in similar ways as does tyrosine depletion.

Study design

The study will be conducted according to a double-blind, placebo-controlled, 3-way cross-over design.

Intervention

Participants will be treated with histidine depletion, tyrosine depletion, or a placebo. All treatments are provided to the volunteer as a drink. The treatment order will be established by complete counterbalancing.

Study burden and risks

The time investment for the participants will be around 24 hours in total, which is comprised of 1) medical assessment by questionnaire (around 1 hour), 2) training session in which the tasks will be practised (around 2 hours), and 3) three test sessions of around 7 hours. The day before a recording, the participants may not eat and drink after 10 o*clock PM, except for water. Furthermore, they are not allowed to drink any alcohol. On each test day, the participants will follow a protein-low diet. At the beginning of a test day, a catheter is placed to be able to take blood samples at 5 different time points.

Contacts

Public

Universiteit Maastricht

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

male or female, between 18 and 35 years of age, healthy (absence of exclusion criteria), normal static binocular acuity, body mass index between 18.5 and 30, willingness to sign an informed consent.

Exclusion criteria

history of cardiac, hepatic, renal, pulmonary, neurological, gastrointestinal, haematological or psychiatric illness, excessive drinking (>20 glasses of alcohol containing beverages a week), pregnancy or lactation, use of medication other than oral contraceptives, use of recreational drugs from 2 weeks before until the end of the experiment, and any sensory or motor deficits which could reasonably be expected to affect test performance. Those volunteers who have a first-degree relative with a psychiatric disorder or a history of a psychiatric disorder will also be excluded.

Study design

Design

Study type: Interventional

Masking: Double blinded (masking used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-02-2007

Enrollment: 18

Type: Actual

Ethics review

Approved WMO

Date: 28-12-2006

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 NL15303.068.06