

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

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	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

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**

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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