# Effect of S-Ketamine on Body Perception in Healthy Adults

Published: 13-10-2023
Last updated: 21-12-2024

The aim of this project is to assess the acute effects of the N-methyl-D-aspartate receptor antagonist S(+)-Ketamine compared to placebo on body and self-perception, using cognitive experimental tasks and EEG in healthy volunteers.

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Mood disorders and disturbances NEC |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON53181

**Source**
ToetsingOnline

**Brief title**
S-Ketamine on body perception - the ESKOP study

### Condition

- Mood disorders and disturbances NEC

**Synonym**
The research will be conducted with healthy volunteers and no patients are involved.

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universiteit Leiden
**Source(s) of monetary or material Support:** NWO VIDI Project 'Putting Psychedelics in Perspective'

## Intervention

**Keyword:** body perception, psychopharmacology, S-ketamine

## Outcome measures

### Primary outcome

The primary outcome measures are the neural and behavioral effects of S-ketamine relative to placebo. Specifically, we examine the neural effects of S-ketamine on event-related potentials (ERPS) in a sensory suppression task and in a trait-adjective task. Additionally, we examine the effects of S-ketamine on perception of peripersonal space, feelings of feelings of embodiment and perception of heart rate, through behavioral-experimental tasks and measurements.

### Secondary outcome

The secondary outcome measures of this study are the effects of S-ketamine on subjective perception, measured by questionnaires and an interview; the relationship between the subjective measures and neural and behavioral effects; and the relationship between personality factors and subjective effects.

# Study description

### Background summary

The selective NMDA-antagonist ketamine is widely used as a general anesthetic and is increasingly being prescribed as an anti-depressant for patients suffering from major depressive disorder (MDD). Whereas ketamine*s psychotropic effects, including feelings of dissociation, disembodiment and derealization, have long been considered side-effects, recent evidence indicates that ketamine-induced changes in body and self-perception may contribute to its therapeutic efficacy. Addressing these changes and their underlying neurocognitive mechanisms, bears relevance for the understanding of other

disorders that are also characterized by aberrant processing of interoceptive and exteroceptive bodily signals, such as anxiety, post-traumatic stress disorder and anorexia nervosa. To this end, the current study integrates previous neurochemical models of ketamine with recent computational and Bayesian models of body- and self-perception. By using state-of-the-art experimental cognitive tasks combined with electroencephalogaphy (EEG) measures, central predictions regarding the neurocognitive mechanisms underlying ketamine-induced changes in body perception will be assessed. Thereby this study will extend our knowledge about the primary mechanisms of action of ketamine, the neurocognitive basis of bodily self-consciousness and its relation to clinical disorders.

## Study objective

The aim of this project is to assess the acute effects of the N-methyl-D-aspartate receptor antagonist S(+)-Ketamine compared to placebo on body and self-perception, using cognitive experimental tasks and EEG in healthy volunteers.

## Study design

This study uses a within-subjects double-blind cross-over experimental design. Participants will participate in two experimental sessions, in which they receive either S(+)-ketamine or saline.

## Intervention

In the S(+)-ketamine session, subjects will receive an intravenous (IV) administration of a continuous infusion of 20 mg /h (per 70 kg) for 1 hour, followed by an infusion of 30 mg /h (per 70 kg) for 1.5 hours. In the placebo session, participants will receive an IV administration of 50ml of saline solution.

## Study burden and risks

In total the study consists of a 20-minute screening, and two times a 5-hour experimental session in the lab, followed by an exit interview. During the lab-visits, subjects will conduct approximately 2 hours of questionnaires and different experimental tasks, and EEG measures will be recorded. The doses of S(+)-ketamine used in this study are moderate and comparable to those used in previous studies at the LUMC. The outcomes of the study will provide new insight in the neurocognitive mechanisms underlying the acute effects of ketamine on body and self-perception. Participants will receive a reimbursement of ¤220 for completion of the study.

# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)

## Inclusion criteria

1. Healthy male or female volunteers; 2. Age: 18 - 40 years; 3. Body mass index < 30 kg/m2 4. Able to give informed consent. 5. Be able to speak and understand English.

## Exclusion criteria

1. Known or suspected neuromuscular or a (family) history of any neuromuscular disease 2. A history of allergic reaction to food or medication including study medication 3. Any current or previous medical (including high blood pressure), neurological or psychiatric illness (including a history of anxiety) 4. Alcohol abuse (> 21 units/week) 5. Illicit drug use in the past 30 days before inclusion 6. Pregnancy or lactation 7. Participation in any medical or drug

trial in the month prior to the current study

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Crossover |
| Masking: | Double blinded (masking used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 14-10-2024 |
| Enrollment: | 24 |
| Type: | Actual |

# Ethics review

Approved WMO

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|---|---|
| Date: | 13-10-2023 |
| Application type: | First submission |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>metc-ldd@lumc.nl |

Approved WMO

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|---|---|
| Date: | 27-05-2024 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>metc-ldd@lumc.nl |

Approved WMO

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|---|---|
| Date: | 07-11-2024 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>metc-ldd@lumc.nl |

# 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 | NL84218.058.23 |