What happens to human information processing during anesthesia: the effect of a sub-anesthetic dose of S-Ketamine

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

Summary

ID

NL-OMON36679

Source
ToetsingOnline

Brief title
Effects of S-Ketamine on Information processing

Condition

- Other condition

Synonym
Anesthesia, loss of consciousness

Health condition

geen aandoening, neurologische werking van anesthesie

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Amsterdam
Source(s) of monetary or material Support: European Research Council

Intervention

Keyword: Consciousness/Anesthesia, fMRI, Neural mechanisms, S-Ketamine

Outcome measures

Primary outcome

(a) fMRI, BOLD activation patterns, (b) cognitive task performance (visual

short-term memory, motion induced blindness, backward masking)

Secondary outcome

nvt

Study description

Background summary

For nearly two centuries, we use general anesthesia for routinely extinguishing consciousness during surgery. Yet, we do not know how consciousness arises in the brain and what information is still present when people are under anesthesia. However, it has been shown that with anesthesia not all information processing is disrupted, some activity remains. The question we want to answer is how much information the remaining activity still contains. To answer this question, we will manipulate the level of information processing in different ways. We will use a sub-anesthetic dose of S-Ketamine, that is commonly used in anesthesia and different behavioral task to manipulate information processing. By comparing the neural responses (using fMRI) and behavior between different manipulations it is possible to infer which part of the information processing is affected and which is not.

Study objective

In a fMRI experiment, will measure the changes in brain activity patterns and in functional connectivity. We hypothesize that a subanesthetic dose of S-Ketamine impairs the functional connectivity, especially the feedback connections that are important for consciousness to arise. Furthermore, we

expect that S-Ketamine will not affect the decoding of brain activity patterns in the specific object related brain areas. But that S-Ketamine will impair decoding in other brain areas where the information was not integrated. To manipulate the decoding further, the visibility of the stimuli will be reduced with masking. We predict that masking will have similar effects as S-Ketamine, no effects in the object related areas but reduced decoding possibilities in other brain areas. The final part will look at the effects of S-Ketamine on different manipulations of conscious perception, especially task that require different levels of information processing and different stages of consciousness (visual short-term memory task, a backward masking task, and a motion induce blindness task).

Study design

This double blind placebo controlled within-subject trial contains two sessions (placebo and S-Ketamine). The order of the sessions will be random.

Study burden and risks

Subjects participate in 2 sessions with 1 week in between the sessions. Before the participants are enrolled in the study, they will be thoroughly screened by a psychiatrist to minimize any risk associated with participation. Furthermore, the subjects will be well informed and will practice the tasks before the sessions.
A psychiatrist/anesthesiologist will be present throughout the experiment to monitor the participant. The participants are asked not to eat and drink 1 h prior to the study and to refrain from caffeine containing drinks for 3 hrs. Heart Rate and Blood pressure will be measured. Furthermore, Visual analogues scales will be used to assess the mood and state of the subjects. The given dose of S-Ketamine is a low dose with minimal chance on side effects. In the anesthesiology department there is a lot of experience with this type of recordings and it is not regarded as burdening for the participants. We regard this protocol as a reasonable load on this group of participants, with negligible risks.

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, aged between 18-30 years;-corrected to normal vision;-Written informed consent.;-Screening for fMRI;-Psychiatric Screening;-Screening contra indications S-Ketamine

Exclusion criteria

- Inability to speak Dutch or English;- Drug or alcohol abuse over a period of six months prior to the experiment;- History of closed-head injury;- With respect to MRI imaging: claustrophobia; presence of non-removable metal objects, use of psychotropic medication.;- Multiple serious drug allergies;- Use of psychopharmaca.;- Serious neurological or psychiatric disorders;- Recreational psychotrope drugs or psychoactive drugs use in the past 30 days;- Colour blindness;

Study design

Design

Study type: Observational invasive

Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-05-2012
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Ketanest-S
Generic name:	Ketanest-S
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	12-01-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-02-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2011-000024-15-NL
CCMO	NL35293.018.11