Do you want to participate in a study on ketamine?

## The aim of the project and why you have been contacted

Do you want to participate in a scientific study led by the university of Oslo investigating markers of experiences during ketamine infusion?

Consciousness contains everything we experience sensory data, emotions, thoughts, and memories. Still, as a phenomenon, consciousness is a mystery that the natural sciences cannot provide a satisfactory answer to. To measure consciousness, we need to measure the brain in conditions in which consciousness can be assumed to have changed. This occurs, for instance, during anesthesia, where consciousness appears to be missing or altered. Therefore, we wish to test different candidate measured based on brain wave recordings during wakefulness and anesthesia.

The reason we are administering ketamine is that it is provided as a treatment against depression at Østfold hospital. However, research is lacking on the optimization of this treatment. Around 50% experience positive effects from the infusion, but it is unclear why this is not true for all. In this study, we want to construct markers of ketamine infusion that map to specific experiences or states. Clinicians can then use these markers to calibrate treatment conditions in order to increase the positive effect of ketamine treatment against depression.

## What does the study entail for you?

The study requires you to spend 6-7 hours with us. Travel time is around 1 hour depending on traffic, preparation takes 1 hour, and the ketamine infusion is around 1-2 hours. After ketamine administration, it is common to feel dizzy or nauseous for some time. You will therefore relax for about 1-2 hours after ketamine administration is completed, or until you feel well enough to go back to Oslo.

We will immediately start prepping for the EEG session when we arrive at Kongsberg by measuring your head circumference and finding an appropriate cap with electrodes attached. Then we will ensure good connectivity with our electrodes and your brain signals. During this phase, we will ask you to complete a few questionnaires about your general mood and expectations. Following this, the anesthesiologist will start calibrating and infusing the correct dose. We will ask you to count upwards from 1 to as long as possible during this part. This will help us find a suitable dose. When this is achieved, the main part of the study has begun. During the ketamine infusion, we will attempt to contact you at regular intervals and ask you to answer rudimentary questions to assess cognitive functioning and to what you have experienced, if anything. After around 1 hour, the session is complete, and we will start the last phase which includes some questions regarding your experience and what you can remember from the experiment. We will clean up our equipment, collect data, and drive back to Oslo after you have rested. It is normal to feel nauseous after such sessions, so if you need additional time before driving back, that is fine. However, you can not operate heavy machinery or motorized vehicles the rest of the day. We will drive you to Kongsberg and back in our car; therefore, we require that you meet us at Blindern campus: Domus Medica tilbygg (Gaustadalleen 34, 0373 Oslo).

**We will also require you not to eat or drink anything but water prior to the session (or 6 hours before the infusion start). You can drink water up to 2 hours before the infusion start**. This gives the best result with ketamine. In addition, we would prefer if you wash your hair with shampoo the morning of the experiment, but without using conditioner or any other hair products. This will ensure good recordings with electroencephalography (EEG). You will be allowed to eat and drink after the end of the experiment.

In this project, we will collect and register information about you. All of this information will be de-identified. All the information you registered during the recruitment phase, i.e., in Nettskjema, will not be stored. All of the researchers and hospital employees involved in the project have a duty of confidentiality, meaning that they are not permitted to disclose medical information about you to others without your consent, or unless they are permitted to do so by law.

### Questionnaires

Before the session begins, we will ask you about how you are doing on that day, your expectations and worries, and some background information about you. You will be asked about your current mood, stress levels, and expectations. We will also ask about your sex, gender, age, height, weight, and drug habits. In addition, we will go through questions concerning overall current health and the history of certain illnesses. This information will explain anomalies in our data and ensure that you satisfy our inclusion and exclusion criteria. The data will not be shared beyond the research team and will be de-identified at the end of the experiment session.

During the session, you will regularly be asked about your experience, basic geography, and simple memory tasks.

When the session is finished, we will ask you about the experience. You will receive questions about how it changed your self-understanding, your degree of psychological insight, and whether it was emotionally challenging.

### EEG-measurements

A central part of this research is the electroencephalographic (EEG) measurements of brain activity. This includes receiving a cap with attached electrodes that we will place on your head. These electrodes receive electrical inputs from your skull through the water-soluble gel. This safe method is used across the globe and entails no risks or discomfort for you other than wearing a tight EEG cap. EEG passively measures brain signals generated by your brain from the ketamine infusion. This way, we can investigate possible changes in brain activity during the infusion and explore how your brain activity correlates with your experience. After the treatment, you can wash the gel from your scalp and hair.

### Ketamine infusion

Ketamine is a commonly used anesthetic in Norway due to its safety characteristics. One such benefit is that patients undergoing ketamine anesthesia can breathe freely. The regimen employed during the study will not include any anesthetics in conjunction with ketamine to measure the effect of ketamine alone on neural dynamics and cognition. One effect of ketamine anesthesia is the chance to experience ‘vivid dreams’ during sedation. This is completely normal. Another potential side-effect is that you might feel nausea, dizziness, or blurred vision following sedation. This passes over time, and we will ensure that you can rest following the experiment. For this reason, you cannot operate heavy machinery or drive motorized vehicles the rest of the day.

## Possible advantages and disadvantages

For you, there are no major advantages to participating in the study besides contributing to improving ketamine therapy and theoretical science, and to experiencing a novel state of being in a controlled setting.

## Voluntary participation and option to retract consent

It is voluntary to participate in the project. If you wish to participate, please register at this link: [Ketamine study sign up v2 - Nettskjema](https://nettskjema.no/a/302542#/page/1). You can drop out of the study whenever you want, without giving any reason for doing this. It will not have any negative consequences for you. You can demand to see the information saved about you, which will be handed out within 30 days. You can also require that all the information about you should be deleted. If anything is unclear in this study description, please email [andreasliemassey@gmail.com](mailto:andreasliemassey@gmail.com).

The right to require data destruction is only valid before the data has been analyzed or published; after this, it can no longer be deleted because it is impossible to determine your data materiale.

## What will happen with your information?

The information registered about you will be used as described under “aim of study” and will be used until July 1, 2023. Potential usage and storage time extensions will only occur after approval from REK and other controlling bodies. You have the right to know what information has been stored about you and to correct potential errors. You also have the right to view the security measures taken while processing your information. You can also complain about processing your information to Datatilsynet and the institution’s data protection officer.

All your information will be processed without a name, social security number, or other directly identifying information. Your participant number and data points are the only information connecting your brain activity data to your questionnaire data. None of the former contain any directly identifying data.

Publication of the results is a necessary part of the research process. All publications will ensure that single participants will not be identifiable through the reporting of the data.

After the research project is finished, information about you will be stored for up to five years based on control considerations, but without personally identifiable information.

## Who is allowed to participate?

You may participate in this study if none of the following applies to you and you are between 18-30 years old:

* Heart or cardiovascular disease
* Irregular or high resting pulse (above 90 beats per minute)
* Bleeding tendency or risk for blood clots
* Serious infectious disease or contagious disease
* Currently have or have had a neurological or psychological illness like bipolar disorder, schizophrenia, mania or other reality distorting disorder.
* Relatives (immediate family, cousins, uncles & aunts, grandparents) who has or have had the above neurological or psychological illnesses
* Take the following medications: Tricyclic antidepressants, lithium, SSRIs, antipsychotic medication haloperidol, or monoamine oxidase inhibitors
* Pregnant or breastfeeding

## Sharing of information and transfer to foreign countries

As a part of conducting this project, it is necessary to transfer your data to researchers in other countries. This information includes EEG data and questionnaire responses. This will not be personally identifiable information and will only be used for analyses as a part of a larger database of similar data. Currently, there are no clear plans for this, but the Psychological Institute and Institute of Medicine collaborate with universities in Milan (Italy) and Liege (Belgium). Furthermore, EEG data and general information from questionnaires might be included in open databases for research, but this will not be traceable to you as an individual. The Psychological Institute is responsible for transferring the information to occur in accordance with Norwegian law and the EU’s GDPR laws.

## Insurance

The university is self-insured.

## Approvals

The regional committee of medicine and health-related research Ethics (REK) has conducted an evaluation and approved the project. Case number from REK: 481020 and 2015/1520.

The Institute of Basic Medical Sciences at the University of Oslo and project leader Johan Storm are responsible for data protection in this project.

We process the information based on the participant’s expressed consent.

## Contact information

If you have questions about the project or wish to retract your participation, please contact Andreas Lie Massey (Tlf: 98116824, Email: [a.l.massey@medisin.uio.no](mailto:a.l.massey@medisin.uio.no)) or Andre Sevenius (Tlf: 90804477, Email: [sevenius.nilsen@gmail.com](mailto:sevenius.nilsen@gmail.com)).

If you have any questions about privacy in this project, you can contact the data protection officer at the Psychological Institute, University of Oslo: Torgrim Mikal Langleite (Email: [t.m.langleite@psykologi.uio.no](mailto:t.m.langleite@psykologi.uio.no))

## Sign up

To sign up for the research project; please register your interest at nettskjema: [Ketamine study sign up v2 - Nettskjema](https://nettskjema.no/a/302542#/page/1) and send an email to [a.l.massey@medisin.uio.no](mailto:a.l.massey@medisin.uio.no).

## Consent form for participation in the research project

I CONSENT TO PARTICIPATING IN THIS PROJECT AND TO MY PERSONAL INFORMATION BEING USED IN THE WAY IT HAS BEEN DESCRIBED ABOVE.

| Place and date | Participant’s signature |
| --- | --- |
|  |  |
|  | Participant’s name with capital letters |

I confirm that I have informed about the study

| Place and date | Signature |
| --- | --- |
|  |  |
|  | Role in the project |