Universitätsspital Basel

Neurologische Klinik und Poliklinik

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Enquiry to participate in medical research:

Symptoms of disorientation in people with nystagmus

Dear member,

We enquire whether you would be willing to participate in our research project.

Participation is optional. All data collected in this research project are subject to strict data protection rules.

The research project is conducted by Dr Heiko Rust. If you are interested we will inform you about the results of this research project.

In a phone conversation we will explain the main points and answer your questions. In order for you to be able to get an idea we provide you with the most important facts first. Following this we provide you with further, more detailed information.

Why do we conduct this research project?

- We want to find out to what extent people with inborn or acquired shaking of the eyes (nystagmus) are more or less susceptible to develop disorientation symptoms compared to the general population.

What do I have to do if I volunteer to take part? – What happens to me if I take part?

- Method of participation: If you decide to take part, Dr Rust will ring and ask you questions during a brief phone call concerning your eye movement disorder, possible migraine and susceptibility to disorientation symptoms.

- Process of participation: We will send you a list of questions which we will be asking by email. After this there will be a single phone call to answer these questions, maximum duration 10 minutes. Since we are not able to examine your eye movements it would be ideal to have a video of your eye movements. We therefore will ask you to video your eye movements during head movements with your smart phone in order to document integrity of a reflex of your eyes and your vestibular organ (vestibulo-ocular reflex). This reflex enables stable vision during head movements. Dr Rust will instruct you on how to video your eye movements.
  If you do not want to or cannot video your eye movements you will of course be able to participate in this project.

What are the benefits and risks involved?

Benefits

- There is no direct benefit for you when you participate in this research project.
- With your participation you will help future patients.

Risk and burden

- There is no risk. The collected data and if applicable videos are only accessible to Dr Rust. His colleagues for this study, Prof Palmowski-Wolfe, Prof Golding and Prof Gresty will only be able to see the data after it has been anonymised, in other words all personal identifiers have been removed.

By agreeing to this you confirm that your participation is optional and that you have understood the content of the whole document and that you are free to withdraw from the study at any time without any explanation.

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Detailed information

1. Aim and selection

In this information we refer to our research intent as research project. If you volunteer to take part in this study you will be considered a participant.

In this research project we want to assess to which extent people with inborn or acquired shaking of the eyes (nystagmus) are susceptible to develop symptoms of disorientation compared to the general population. We approach you as all people with nystagmus are eligible to participate in this study.

2. Background information

When humans navigate in their surrounding environment they orient by mainly using information from the eyes, the balance organs in the inner ears and the joint position sense of the body. Disorientation symptoms arise when there is a mismatch in central processing between these types of sensory information. People with nystagmus are likely to encounter symptoms of disorientation in everyday life as their visual and often vestibular perception is changed by the nystagmus itself and / or associated disorders as well as associated changes of the central nervous system. In the underlying study we want to assess whether people with nystagmus are susceptible to disorientation symptoms compared to control subjects without nystagmus.

- The research project will be conducted from the University of Basel Hospital, Switzerland. 40 participants with nystagmus will undergo a survey within a single, maximum 10 minutes phone call.
- We conduct the research according to the laws in Switzerland. Furthermore, we respect all internationally recognized guidelines. The authorized local Swiss Ethical Committee has reviewed and approved this research project.

3. Process

- Single phone call from the University of Basel Hospital. Duration, 10 minutes.
- Additional option to video your eye movements with a smart phone. The video mainly shows your eyes in order to document integrity of the vestibulo-ocular reflex. This reflex enables stable vision during head movements by driving the eyes in the opposite direction of the head movement. Dr Rust will instruct you on how to record the video. If you do not want to or cannot video your eye movements you will of course be able to participate in this project.

4. Benefit

You will not personally benefit from participating.
The results will contribute to understanding of disorientation symptoms arising in people with nystagmus.

5. Participation

You are participating voluntarily. If you do not want to participate in this research project or if you later wish to withdraw your participation, you do not need to provide a reason.

6. Risks and burdens

We do not anticipate any risks for you participating in this study.

7. Results

We aim to produce a report of the findings of this project. You can contact the study physician Dr Heiko Rust via email who can provide you with the final report at the end of this project if you wish.

8. Confidentiality of data processing and encryption

For this research project, personal and health data about you will be collected and processed, partially in a digitized form. When collecting the data, your data will be encrypted. Encryption means that all reference data that could identify you (name, date of birth, etc.) will be deleted and replaced by a code. Persons who do not have access to this key list cannot draw any conclusions about your identity. The key list will always be kept securely in the office of the Principal Investigator, Dr Rust of the University of Basel Hospital.

Only the Principal Investigator, Dr Rust will see your unencrypted data, and only to perform tasks within the scope of the research project. Dr Rust is bound by confidentiality. As a participant you have the right to access your data until it is anonymized and all personal identifiers have been removed. As you could be identified in the video your video recording will be destroyed after evaluation after the end of the study.

Data protection

All specifications for data protection will be strictly adhered to. In case that data related to your personal health are being stored on-site it will be kept in a password protected data bank for research purposes only.

Rights of access during inspections

This research project might be subject of inspection by the competent Ethics Committee. In this case the study physician has to disclose your data for those inspections. All parties involved must maintain absolute confidentiality.

9. Withdrawal

You can withdraw from this research project at any time. In this case all the data that has been collected up until this point will be deleted and the consent form whether on paper or electronic format will be destroyed. Please note this option before participating in this project.

10. Compensation

If you participate in this project there will be no compensation. No costs will arise for you when participating in this research project and the phone called will be made by the University of Basel Hospital.

11. Liability

In case that you should suffer harm from this research project the University of Basel Hospital will be liable which has initiated this research project and is responsible for its conduct. The requirements and the procedure are regulated by law.

12. Financing

This research project is financed in its entirety by the University of Basel Hospital/ Dr Rust.

13. Contact person

You are allowed to pose questions on your participation in this research project. Even in the case of uncertainties that occur during or after completion of this research study please do contact:

Dr. Heiko Rust (project leader)
Consultant Neurologist
Department of Neurology
University of Basel Hospital
Petersgraben 4
CH-4031 Basel
E-Mail: heiko.rust@usb.ch
Tel.: +41 61 55 65213

Declaration of consent

Written consent form for participation in a research project
Please read this form carefully. Please ask in case there is something that you do not understand or that you want to know. For participation your written consent is mandatory.

BASEC-Number:	2020-02744
Title of the research project (scientific and plain language):	Symptoms of disorientation in people with nystagmus
Responsible institution (Project leadership and address):	Dr Heiko Rust Neurology University of Basel Hospital Petersgraben 4 CH-4031 Basel
Location of implementation:	University of Basel Hospital
Head of the Research Project at the Study Site: Name and first name in block letters:	Dr Rust, Heiko, Consultant Neurologist
Participant: Name and first name in block letters: Age in years:	

- I have been informed verbally and in writing by the undersigned project leader/study physician about the purpose, the procedure of the research project, the possible advantages and disadvantages, as well as any potential risks.
- I voluntarily participate in this research project and accept the content of the presented written information regarding the above mentioned research project. I was given sufficient time to make my decision.
- My questions in the context of the participation in this research project have been answered I keep the written information and receive a copy of my written consent form.
- I agree that the responsible professionals of the project management and the ethics committee responsible for this research project may access my unencrypted data for inspection and control purposes, but strictly maintaining confidentiality.
- I am aware that my health related and personal data can only be passed on in encrypted form for research purposes for this research project. The sponsor ensures that data protection is maintained according to both international and Swiss standards.
- I am free to withdraw at any time and without giving a reason from participation. My further treatment is granted independently from participation in the research project. Those data collected up to this point will be used in the analysis of the research project,
- The institution University of Basel Hospital is liable for any harm.

Site, date _____	Signature participant *Please type your first* X _____ I agree to participate

Investigator confirmation: Hereby I confirm that I have explained the nature, meaning and scope to the participant. I assure to comply with all obligations in connection with this research project according to the laws applicable in Switzerland. In case I should become aware of aspects that might influence the willingness of the participant in the research project I will instantly inform them.

Site, date _____	Name and first name of the investigator in block letters Rust, Heiko Signature of the investigator