UniversityHospital Zurich

Institute of Neuropathology

Therapeutic Autoantibodies Against Prion Disease From PRNP Mutation Carriers

study information

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Dear Madam or Sir

1. Who we are

We are researchers at the Institute of Neuropathology, University Hospital of Zurich, Zurich, Switzerland. We are in charge of the research project entitled "Therapeutic autoantibodies against prion disease from PRNP mutation carriers", short: "THAUTAN-MC". This study is approved by the Cantonal Ethics Committee of the Canton of Zurich, Switzerland under the permit KEK-ZH 2015-0514.

2. Purpose of the research

Prion diseases (PrD) are inexorably fatal neurodegenerative disorders affecting humans and other mammals. Patients with a mutation in the PRNP gene suffer from a particular type of PrD, namely genetic prion disease (gPrD). Although they are carrying a mutated gene throughout their whole life, symptoms usually occur in high age, indicative of protective factors. We believe these protective factors to be antibodies.

Protective antibodies from humans have shown to harbor superior safety profiles when compared to "commonly" derived antibodies, e.g. from mice, bacteria etc. We propose to identify, produce and validate those antibodies from gPrD patients and eventually carry out a clinical trail against prion diseases.

3. Why we are contacting you

We are writing to invite you to help medical research.

You might give physical material such as blood voluntarily for this study (according to your local ethics laws and statutes) or as part of a medical treatment. We would like to re-use this physical material and genetic data for our research project.

We are therefore asking you to allow your doctor/your nurse to send us this physical material and genetic data for our research project in pseudo-anonymized form. "Pseudo-anonymized" means that you can be identified through your doctor/your nurse by this data, but only your age, gender and clinical data are provided to the researchers, who cannot identify you.

4. Type of Research Intervention

This research will involve the re-use of a maximum of 60 milliliters of already collected blood or a venipuncture in your arm/forearm to collect venous blood. We will test the blood for antibody levels against the prion protein. From every sample, we will collect blood cells in order to determine the genetic information of the antibodies. We will also determine the mutation status of each individual. We respect the patient's wishes of not knowing their mutation status and will not reveal the results of genetic testing.

5. Participant selection

All individuals from families with known history of genetic prion diseases are encouraged to enroll as well as positively tested mutation carriers and their families. Negatively tested individuals from families with genetic prion are welcome to enroll.

6. Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. You may change your mind later and stop participating even if you agreed earlier. You should only release your data and physical material if you wish to do so. Nobody may force you to do so in any way, or attempt to persuade you. You do not have to give reasons for refusing.
You can ask any questions you like about the research project at any time. To do this, please contact the person named at the end of this information document. You can also contact other people working on the project.

7. Ethical issues

In order to participate in our study, you need to sign a Material Transfer Agreement, that will be handed to you upon request. Furthermore, we will not collect blood in our clinic. If you are interested in participating, you need to ask your local ethics committee / institutional review board (IRB) about local laws and statutes to do so. In order to participate in our study we further need a copy of an IRB approval or a

written statement by you that no IRB approval is necessary to collect and analyze the blood (if applicable).

8. Confidentiality

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. The researchers will only know what your number is and will not be able to identify you. We will lock that information up with a lock and key. It will not be shared with or given to anyone except in in pseudo-anonymized form (see above). "Pseudo-anonymized" means that scientific collaborators, review boards etc. can only view your number and its assigned clinical data, but they cannot identify you.

9. Sharing the Results

Confidential information will not be shared. There will be small meetings in the scientific community where no identities will be revealed. After these meetings, we will publish the results in order that other interested people may learn from our research.

10. Commercial exploitation of research data

My consent does not release the organizers of the study from any liability or duties on their part and I retain all rights under law. I have been informed that the new scientific data generated in the study, any licensing agreement notwithstanding, may be freely used in the future for scientific research into autoimmune diseases or the development of treatments. The University of Zurich may grant a license to further develop the research data obtained to a company for commercial exploitation. The legal protection of patients and the confidentiality of data will be safeguarded in all development. No financial reimbursements will be provided for individuals participating in the framework of this study.

11. Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research under the aforementioned conditions.

Print Name of Participant _____

Signature of Participant _____

Pseudo-anonymized code of the Participant _____

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this study information sheet has been provided to the participant.

Print Name of Researcher/person taking the consent

_____

Signature of Researcher /person taking the consent

_____

Date _____
Day/month/year