Participant information and informed consent for participation in a scientific study

„Central programming in patients with a bionic hand after traumatic brachial plexus injury“

Dear participant,

We hereby invite you to participate in the above mentioned scientific study. The explanation of this study will follow in an extensive conversation with the investigator.

Your participation in this study is voluntary. You can decide to withdraw from particpation at any time without having to state a reason for withdrawal. Withdrawal from study participation or stopping before its end will not have any effect on your medical care.

Scientific studies are necessary to acquire reliable new medical research results. Essential for performing such a study is that you declare your agreement for participation in writing. Please read the following explanation of the study carefully as preperation for your conversation with the investigator. Please do not hesitate to ask questions about it.

Please sign the informed consent form at the end of this document only when:

- You completely understand the nature and procedure of the study,
- You are willing to and agree to participate and
- Your rights as a participant in this study are clear to you.

The Medical Ethics Committee of the Medical University Vienna has approved this research study, as well as the participant information and informed consent form.

1. Wat is the aim of the study?

The aim of this study is to acquire a better understanding of how the brain adapts after extensive nerve damage of the upper extremity such as in brachial plexus lesions. The brachial plexus is the nerve network that connects the cervical spine to the arm and hand. A lesion of the brachial plexus can lead to paresis and even paralysis but also to a disturbed sensibility of the affected hand.

For this purpose we want to compare a group of patients with a paralytic hand due to a traumatic brachial plexus lesion who have acquired a bionic hand and a group of healthy control subjects. We also want to investigate a group of patients who have a brachial plexus lesion but have not acquired the hand prosthesis yet, and compare them to the other two groups. We will compare

brain activity between these three groups with Magnetic Resonance Imaging (MRI). In this way we hope to understand better how the brain changes after nerve injury and how it adapts to the use of a hand prosthesis after amputation of the functionless hand. We want to investigate the brain changes in two ways: structurally (are there new connections between the involved brain regions?), and functionally (how do the involved brain regions communicate with each other or activate given the existing connections?). This new knowledge can help us in the long term to improve the treatment of patients with a nerve injury, with and without a hand prosthesis.

2. What happens during the investigation?

This study is performed at the Medical University of Vienna by the departments of Radiology and Nuclear Medicine, and the department of Surgery. We estimate to investigate in total approximately 16 participants. These participants will be from one of the three following groups:

- People with a nerve injury of the upper extremity (for example brachial plexus lesion) which is so severe that they are unable to move the affected hand.
- People with a severe nerve injury as described above but who have also acquired an amputation of the functionless hand and a prosthesis replacement.
- Healthy subjects without any limitations in the upper extremity function.

Your participations in this study is estimated to take two to three hours. Only one visit to the hospital is intended for the investigation.

<u>The following measurements will be conducted solely for research study purposes:</u>

During the study the following examinations will be performed a single time: measurement of the muscle activity of your lower arm (or stump), as well as Magnetic Resonanse Imaging (MRI) of your brain. You are therefore requested to come to the Genereal Hospital in Vienna (Allgemeines Krankenhaus der Stadt Wien or AKH). Only one visit to the hospital is required. Compliance with the instructions during the whole hospital visit is essential for the succesful completion of the study.

At the beginning of the investigation we will go through this agreement in detail with you to make sure that everything is clear and all your questions have been answered. After you have signed the agreement, the investigator who informed you will do so as well. After that you can expect the following two parts of the examination:

EMG training

Before we measure your brain activation, you will first train the movements you are requested to perform in the MRI and the corresponding muscle activation. While you perform the movements you will be able to see the activation of the muscles in your forearm (or stump). For this purpose we will use electromyography (EMG) biofeedback. To measure the muscle activation we will use surface electrodes which are attached to the skin of your forearm (or stump). With this EMG biofeedback you can see the muscle activation as a line on a computer screen in front of you. In this way you can practice the tasks requested from you later in the MRI which are a variation of

closing the hand. With the EMG we will also record your muscle activity in order to later on be able to correctly interpret the MRI findings and verify that you have activated the muscles as requested.

MRI scanning

Before the MRI scanning starts you will be requested to change clothes. We will provide a gown to ensure that there are no metal or magnetic parts in your clothing. Such parts can disrupt the MRI scans and even damage the MRI scanner itself. During MRI scanning you will be lying on your back on the MRI table. Your arms will be placed in a for you comfortable position beside your body and small sand bags will be placed over your forearms to prevent their movement. This is important for the quality of the acquired images. We will also provide ear protection because the MRI scanner is relatively loud. During MRI scanning you will see on a mirror in front of your eyes the images which indicate which task to perform. You will be requested to either squeeze your left or right fist or only to imagine this movement. During scanning the research team can see you and talk to you through a microphone. There is also an alarm button which you can press if you do not feel well.

3. What are the benefits of participation in this scientific research?

No benefits for your health are to be expected from participation in this study. However, with this study we want to achieve a better understanding of how specific brain areas change after a severe nerve injury of the upper extremity and also when it is followed by acquiring a prosthesis. In this way we hope to improve the treatment of these patients in the future.

4. Are there any risks, disadvantages or side effects?

No risks, disadvantages or side effects are expected from participation in this study. None of the used measurements are painful. All measurements are non invasive. This means that at no time will the skin surface be penetrated.
It is necessary to answer our questions precisely prior to the start of the MRI investigation as it may have undesirable side effects in certain cases. For example, in the case you have claustrophobia or there were any issues during a previous MRI scan, we will exclude you from participation to prevent possible risks or disadvantages.

5. Additional use of any medication?

No extra medication will be used during this study.

6. What happens if any symptoms, side effects and/or injury occur?

If at any time symptoms, side effects or any injury occur, you should inform your doctor. In the case of serious side effects, you should inform them if necessary by telephone (please see the contact information below).

7. Insurance

There is an insurance for you as a study participant, irrespective of the responsible party, which covers all costs that have been caused by participation in the study concerning your life or health, excluding changes in the genetic material in germ line cells.

The contracted insurance company is 'Zürich Versicherung' (Schwarzenbergplatz 15, 1010 Vienna; Telephone number: 08000 80 80 80). You can request to view the insurance information. The insurance policy number is 07229622-2 with a validity from 1.10.2020 to 1.10.2021.

In the case of injury you can contact the insurance company directly and report the claim yourself. Austrian law applies to the insurance contract, the insurance claim is in effect in Austria.

For support you can contact the patient advocacy, agency or ombudsman.

In order not to jeopardize the insurance covarage

- You may undergo a new medical treatment during participation in this study only after approval from the for the study responsible doctor (emergencies are thereof excluded). This also applies to additional medication or participation in another research study.

- You have to inform immediately your treating doctor or the above mentioned insurance company in the case of health damage possibly due to participation in this study.

- You have to do everything within the reasonable to clarify the cause, course and consequences of a possible event which requires the insurance and to keep the resulting damage limited. This includes also if necessary giving permission to your treating doctor to share for this purpose requested information with the insurance company.

8. In which case will the study be prematurely stopped?

You can at all times withdraw from particpitaion, retract participation consent and stop with the study without having to state a reason for this and without any following disadvantages for you further medical treatment.

The investigator will inform you immediately about any new findings that occur during the study which may be of importance to you. Considering this information you can revise your decision for **further** study participation.

It is also possible that the investigator decides to end your study participation prematurely, without obtaining your agreement prior to this. The reasons for this can be:

a) You can not comply with the study requirements;

b) The investigator has the impression that further study participation is not in your best interest.

9. Data protection

As part of this study your data will be collected and processed. Data can in principle be categorized as follows:

1) Personal data, which can identify a person directly (for example name, birth date, address, social security number, photographs, etc.),
2) Pseudonymized personal data, which is data that prevents tracing it back to the specific person either by using a code (for example a number), or (for example in the case of images) making it unrecognizable. Despite taking such precautions it is not entirely impossible to re-identify the person without permission.
3) Annonymized data, which makes tracing it back to a specific person impossible.

Access to the data which identifies you directly (see point 1) is only available to the lead investigator of this study and his colleagues that are involved in the study or your medical treatment. Additionally, access may be necessary or requested for verification of the proper study execution by authorized and bound by confidentiality representatives of the Sponsor (Medical University of Vienna), such as representatives of domestic and/or foreign health authorities. All persons that acquire access to the data are subject to the for this purpose applicable national and EU data protection laws and regulations.

The code that allows tracing the pseudonymized data to your personal data will only be saved at centre of your study participation.

Transfer of data occurs only in pseudonymized or anonymized form.

For any publications only the pseudonymized or anonymized data will be used.

As part of this study no transfer of data is expected to countries outside of the EU (a third country).

Your consent forms the legal basis for processing your personal data. You can withdraw your consent for the inquiry into and processing of your data at all times without having to state a reason for this. After your withdrawal no further data will be collected. The data collected untill your withdrawal can however be processed as part of the study.

According to EU laws and regulations (EU-Datenschutz-Grundverordnung or DSGVO) you have in principle the right of information, rectification, deletion, limitation of processing, data transfer and opposition, as far as this does not make the aim of the study impossible or impairs it seriously and as far as no other legal requirements are contradicted by this.

The expected duration of the study is one year. The duration of data storage of your data after the study has ended or has been discontinued is determined by the corresponding legislation.

In case you have questions regarding the handling your data in this study you can ask your investigator to start with. The investigator can forward your concerns if necessary to the persons who are responsible for your data protection.

Contact information of the representatives for data protection of the participating institutions in this study:

Representatives for data protection of MedUni Wien: datenschutz@meduniwien.ac.at

Persons responsible for data protection in AKH: datenschutz@akhwien.at

You have the right to submit a complaint about the handling of your data to the data protection authority (www.dsb.gv.at; E-Mail: dsb@dsb.gv.at).

10. Are there any costs connected to participation? Is there a reimbursement of any costs or another type of compensation?

No additional costs arise from participation in this study. For participation in this study you will recieve a reimbursement of 10 euro's per hour of time participated, as well as a compensation for your travelling costs (public transport, second-class train or car).

11. Possibility to discuss further questions

The lead investigator and his colleagues are available to answer any further questions regarding this study. Also questions concerning your rights as a participant in this research study can be answered.

Name of contact person:	Univ.-Prof. Dr. Oskar Aszmann
Reachable at:	oskar.azsmann@meduniwien.ac.at or 0043 1 40400 69940
Name of contact person:	Dr. Galia V. Anguelova
Reachable at:	galia_anguelova@yahoo.co.uk
Name of contact person:	Dr. Agnes Sturma
Always reachable at:	agnes.sturma@meduniwien.ac.at or 0043 1 40400 61098
Name of contact person:	Anna Bösendorfer
Reachable at:	anna.boesendorfer@meduniwien.ac.at
Name of contact person:	Univ.-Prof. Dr. Gregor Kasprian
Reachable at:	gregor.kasprian@meduniwien.ac.at
Name of contact person:	Victor Schmidbauer
Reachable at:	victor.schmidbauer@meduniwien.ac.at
Name of contact person:	Mehmet Salih Yildirim
Reachable at:	mehmet.yildirim@meduniwien.ac.at

12. Should other treating doctors be informed of participation in this study?

As the study measurement takes place at a single time frame, it is not expected that it will influence any other medical treatment. Besides, only measurements and no medical treatment is involved in the study. However, if you should want to discuss the participation with your treating doctor, please do so.

13. Informed consent

Name of participant:

Birth date:

I hereby declare that I am willing to participate in the research study „**Central programming in patients with a bionic hand after traumatic brachial plexus injury**“. I have been informed that I can withdraw from participation without any disadvantageous effects, specifically for my medical treatment.

I have been extensively and clearly informed about the research study, possible burden and risks, such as my presence, the purpose and duration of the study, and its requirements by Mr/Ms (M.D.) ..... I have furthermore read this participant information and informed consent consisting of in total 8 pages. All of my questions have been answered clearly and satisfactory by the investigator. I have had enough time to make a decision. I do not have any further questions at this moment.

I will follow the investigator's instructions which are necessary for the correct performance of the study, but preserve the right to withdraw at all times from my voluntary participation in this study without any following disadvantages specifically concerning my medical treatment.

I agree in particular that the data collected in this study will be treated as described in the paragraph „Data protection“ of this document.

I have received a copy of this participant information and informed consent. The original stays with the investigator.

.....
(Date and signature of the participant)

.....
(Date, name and signature of the responsible investigator)

(The participant keeps a signed copy of the participant information and informed consent, the original stays in the the study file of the investigators.)