Patient information[1] and declaration of consent for the participation in the clinical trial

Effectiveness of StimaWELL® in patients with chronic neck pain and low-back pain

Dear patient!

We invite you to participate in the above-mentioned clinical trial. The information will be given in a detailed conversation with a medical doctor involved in the study.

Your participation in this clinical trial is voluntary. You can withdraw from the study at any time without giving reasons. The refusal to participate or early withdrawal from this study has no adverse consequences for your medical care.

Clinical trials are necessary to obtain reliable new medical research results. However, an indispensable prerequisite for conducting a clinical trial is that you declare your consent to participate in this clinical trial in writing. Please read the following text carefully as a supplement to the informational meeting with your doctor and do not hesitate to ask questions.

Please sign the declaration of consent only

- if you have fully understood the nature and course of the clinical trial,
- if you are willing to agree to participate, and
- if you are aware of your rights as a participant in this clinical trial.

On this clinical trial, as well as on patient information and declaration of consent, a favourable opinion was issued by the competent ethics committee.

[1] For the better readability, the further text partly dispenses with the simultaneous use of female and male personal terms. Meant and addressed are – if applicable – always both sexes.

1.What is the purpose of the clinical trial?

The purpose of this clinical trial is to record pain intensity in patients with chronic neck and/or low-back pain before and after weekly applied electrotherapy with a newly developed device called StimaWELL®.

Like the clinically often successfully used transcutaneous electrical nerve stimulation, an electrode plate is placed over the entire spine, and a medium-frequent current is applied for 30 min. The weak current leads to an improved blood circulation and relaxation of the muscles, as well as to a subjective feeling of a pleasantly tingling / throbbing / kneading sensation with a feeling of warmth. This is repeated at weekly intervals in a total of six times.

2. Workflow of the clinical trial.

All examinations and therapy sessions are performed by the University Clinic for Anesthesia, Department of Special Pain Therapy in the General Hospital of Vienna, in cooperation with the University Clinic for Physical Medicine and Rehabilitation. A total of approximately 125 patients will participate in the study. All patients are first asked to contact the e-mail address studie_elektrotherapie@hotmail.com for an examination appointment. In the following preliminary examination, inclusion and exclusion criteria are evaluated. Patients who are suitable for participation in the study are then assigned to the weekly electrotherapy sessions and for the follow-up examination.
The methods used in the study consist of:

- the collection of the personal data and medical history (previous diseases, current medication, subjective pain perception)
- Investigation of the mobility of the spine:
  - Cervical spine: head mobility in different levels (front-back-right-left-lateral head inclination using a protractor)
  -Lumbar spine: measurement of the spine while standing, after forward- and backward bending
- Questionnaires for recording the subjective perception of pain, the impairment in daily life, as well as the quality of life.

Your participation in this clinical trial is expected to take about two months in total (in detail: an hour at the beginning and end of the study for the basic and follow-up investigation respectively, as well as 30 minutes at weekly intervals for six times in total for the electrotherapy sessions in between). During electrotherapy, you will lie with your upper body free on a moistened mat that covers your entire spine that creates a weak current flow. To get a more precise statement about the effectiveness of the device, a randomization scheme (elaborated by the statistical outpatient clinic of the Medical University of Vienna, Department of Clinical Biometry) is assigned to group patients in full-term suprathreshold electricity therapy (verum), minor current therapy (i. e. device calibration without consequent electrotherapy; control) or with feigned therapy (controlof control). During the therapy sessions, you will not know in which group you are assigned.

You are asked to come to the General Hospital (AKH) of Vienna, Pain Outpatient Clinic Anesthesia 9I. Compliance with the visiting appointments, including the instructions of the study physician, is crucial to the success of this clinical trial.

3. What is StimaWELL®?

StimaWELL® is a medical device that has recently become CE-certified, but it is not yet clinically in use routinely. It consists of a large electrode mat that generates a weak current flow to the spine area. This medical device is sporadically used for the treatment of chronic back pain caused by muscletension in the spine area, intervertebral disc protrusion, herniated intervertebral disc, etc.). Studies on its use in patients are not yet available. Nevertheless, the application is considered safe, since the device is based on transcutaneous electrical nerve stimulation, which is widely used in clinical practice in various pain conditions and is known to have few side effects.

4. What is the benefit of participating in the clinical trial?

They would receive more intensive pain medicine and physical care, with the option to receive further therapy units with StimaWELL® in the AKH pain outpatient clinic .

5. Are there risks and side effects?

The questionnaires used in the study have been in routine clinical use for many years and are harmless to health. The newly developed electrotherapy device StimaWELL® is CE-certified, and thus classified as safe and released for clinical use. Possible side effects of too intensive use are skin intolerances such as redness or temporary pain enhancement.

The clinical trial was also examined by the responsible ethics committee and positively assessed.

6. Does the participation in the clinical trial have other effects on lifestyle and what obligations do it entail?

No additional pain treatments (except oral intake of painkillers) such as infiltrations ("injections") into the spine, other physical measures such as massage, ultrasound, other electrotherapies such as TENS, mud packs, magnetic field, or exercise therapy should be performed. Furthermore, no unnecessary drug changes (e. g. testing a new drug, unless necessarily indicated) should take place during the study phase. Otherwise, there are no further obligations or effects on lifestyle in the context of the study.

7. Insurance.

As a participant in this clinical trial, you have the statutory insurance coverage independent of fault (personal injury insurance according to § 47 medical devices law, which covers all damage to your life or health that can be caused to your life or health by the measures of the clinical examination carried out on you, except for damage due to changes in the genetic material in cells of the germline.

The insurance was provided for you by Zürich Versicherungs-Aktiengesellschaft (Schwarzenbergplatz 15, A-1010 Vienna; Tel.nr. +43-1- 800 0808080) under the policy number 07229622-2. On request, you can inspect the insurance documents.

In the event of a claim, you can contact the insurer directly and assert your claims independently. Austrian law is applicable to the insurance contract, the insurance claims are enforceable in Austria.

For support, you can also contact the Patient Advocates, Patient Advocacy, Patient Advocacy or Patient Ombudsman.

In order not to endanger the insurance cover

- you may only undergo another medical treatment during the duration of the clinical trial in agreement with your treating investigator (except in **emergencies).** This also applies to the additional intake of medication or participation in another study.
- you must immediately notify the attending investigator - or the insurance company referred to above- of any damage to health which may have occurred as a result of the clinical trial.
- you must do everything reasonable to clarify the cause, course, and consequences of the insurance-case and to keep the damage incurred to a minimum. This may also include allowing your treating physicians to provide the information required by the insurer.

8. Information for women giving birth.

Pregnant and lactating women may NOT participate in this clinical trial. If you nevertheless become pregnant during the clinical trial or suspect that you have become pregnant, please inform your investigator immediately.

9. When will the clinical trial be terminated prematurely?

You can revoke your willingness to participate at any time, even without giving reasons, and withdraw from the clinical examination, without this causing you any disadvantages for your further medical care.

However, it is also possible that your investigator decides to terminate your participation in the clinical trial prematurely without first obtaining your consent. The reasons for this may be:

a) They cannot meet the requirements of the clinical trial.

b) Your attending physician has the impression that further participation in the clinical trial is not in your interest.

10. How will the data collected during this clinical trial be used?

Unless otherwise provided by law, only the auditors and their employees have access to the confidential data in which you are named (personal data). Furthermore, representatives of domestic and foreign health authorities and the responsible ethics committee can inspect this data in order to check the accuracy of the records. These persons are subject to a statutory duty of confidentiality.

The data is passed on at home and abroad exclusively for statistical purposes in encrypted (indirectly personal) or anonymous form, which means that you are not named. Even in any publications of the data of this clinical trial, you will not be named.

The auditors and their employees are subject to the provisions of the Austrian Data Protection Act 2000 in the current version when dealing with the data.

If you withdraw your consent and thus end your participation prematurely, no new data will be collected about you. However, due to legal documentation obligations (Medicines or Medical Devices Act), your personal data may still be inspected for testing purposes by authorized persons obliged to maintain confidentiality for a legally specified period.

11. Are there any costs for the participants? Is there a reimbursement or remuneration?

Your participation in this clinical trial will not incur any additional costs for you, except for the time and additional financial costs caused by the journeys to the AKH.

12. Opportunity to discuss further questions

If you have any further questions in connection with this clinical trial, please do not hesitate to contact your investigators. Questions concerning your rights as a patient and participant in this clinical trial will also be answered.

Names of contact persons:

- Dr. Asami Naka (Anesthesia, Department of Special Pain Therapy)
  Phone: 01-40400-41440
- Dr. Clea Kotz (Anesthesia, Department of Special PainTherapy)
  Phone: 01-40400-41440
- Dr. Edith Gutmann (Anesthesia, Department of Special Pain Therapy)
  Phone: 01-40400-41440
- Ao. Univ.-Prof. Dr. Othmar Schuhfried (Physical Medicine and Rehabilitation)

Phone: 01-40400-43300

- Ao. Univ.-Prof. Dr. Sabine Sator-Katzenschlager (Anesthesia, Department of Special Pain Therapy)
  Phone: 01-40400-41440

13. Declaration of consent

Name of the patient in block letters:.....

Date of birth: ..... code:.....

I agree to participate in the clinical study testing the **effectiveness of StimaWELL® in patients with chronic neck- and low-back pain.**

Mr./Mrs..... has explained in detail and comprehensibly about the study, possible burdens and risks, as well as about the nature, significance and scope of the clinical trial, the existing insurance and the requirements arising from it for me. I have also read the text of this patient education and declaration of consent, which comprises a total of 6 pages. Questions that have arisen have been answered in an understandable way and sufficiently. I had plenty of time to make up my mind. I have no further questions at the moment.

I will comply with the medical orders required to carry out the clinical trial, but I reserve the right to terminate my voluntary participation at any time without this causing me any disadvantage for my further medical care.

At the same time, I agree that the data I have obtained in the course of this clinical trial should be stored. I am aware that in order to check the accuracy of the data recording, representatives of the competent authorities, the ethics committee and, if necessary, the client may inspect my personal disease data at the investigator.

Should I revoke my participation in this study or if my participation in the study is terminated prematurely by the study physician, I agree that the data collected up to this point may continue to be used to the extent necessary to:

1. ensure that my legitimate interests are not affected

and – if applicable –

2. to comply with the legal obligation to submit complete registration documents and the statutory documentation obligations.

When handling the data, the provisions of the Data Protection Act 2000 are observed.
I have received a copy of this patient information and declaration of consent. The original remains with the investigator.

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

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

(The patient receives a signed copy of the patient information and declaration of consent, the original remains in the study folder of the investigator.)