Participant Information and Informed Consent Form for Participation in the Clinical Study

Prospective Multicenter Trial Comparing Open Surgical Decompression versus Minimally Invasive Ultrasound-Guided Carpal Tunnel Release

Dear Participant,

We invite you to participate in the aforementioned clinical study. You will receive detailed medical information during an in-depth informational consultation with a physician.

Your participation in this clinical study is voluntary. You may withdraw from the study at any time without giving reasons. Declining to participate or premature withdrawal from this study will not have any adverse consequences for your ongoing medical care.

Clinical trials are necessary to obtain reliable new medical research findings. However, an essential prerequisite for conducting a clinical study is that you provide your written informed consent to participate in this study.

Please read the following text carefully as a supplement to the informational consultation with your physician, and do not hesitate to ask questions.

Please sign the informed consent form only if you have fully understood the nature and procedure of the clinical study, if you are willing to agree to participate, and if you are fully aware of your rights as a participant in this clinical study.

A favorable ethical opinion for this clinical study, as well as for the patient information and informed consent form, has been issued by the competent Ethics Committee.

What is the purpose of the clinical study?

The aim of this study is to compare two different surgical methods for the treatment of carpal tunnel syndrome: conventional open surgery and a minimally invasive method under ultrasound guidance.

We aim to determine:

- which method leads to a faster recovery,
- which method is more comfortable for patients, and
- whether there are differences regarding pain, hand function, and return to daily activities.

You are being asked to participate in this study because treatment for carpal tunnel syndrome is indicated and planned for you. There are currently several established standard methods to surgically treat this condition. You have already chosen one of the two treatment methods. At the AUVA Trauma Hospital Salzburg (UKH Salzburg), open carpal tunnel release is performed; at the University Institute of Radiology, minimally invasive ultrasound-guided carpal tunnel release is performed. By choosing your respective treatment center, you have decided independently and without external influence on the established and routinely used treatment method offered at that institution.

How is the clinical study conducted?

This clinical study is being conducted at the AUVA Trauma Hospital Salzburg (UKH Salzburg) and the Department of Radiology at the University Hospital Salzburg. A total of 200 participants will take part in this study.

Your participation in this clinical study will last 52 weeks.

The following measures are carried out exclusively for study purposes:

During this clinical study, the following assessments will be performed at intervals of 2, 6, 12, and 52 weeks:

• **Collection of patient data:** Within the scope of this study, your baseline medical data and follow-up data will be recorded. This includes age, sex, affected side, relevant comorbidities, prior treatments, electrophysiological

findings, type of surgery performed, unplanned follow-up treatments, patient satisfaction, and details regarding sick leave / incapacity for work and return to work.

• **Questionnaire completion:** Questionnaires will be administered to evaluate recovery and clinical outcomes.

• **Assessed parameters:** The following parameters will be examined at the specified time points (see table below):

- **Collection of patient scores (SANE, VAS, and BCTQ):** The Boston Carpal Tunnel Questionnaire (BCTQ) assesses typical symptoms of carpal tunnel syndrome and functional limitations of the affected hand in daily life. The Visual Analog Scale (VAS) is used to assess your pain intensity on a numeric/visual scale. The Single Assessment Numeric Evaluation (SANE) score is a simple subjective assessment in which you rate the overall function of your affected hand as a percentage.
- **Patient satisfaction & return to work:** Assessment of patient satisfaction with the surgical method (Likert scale) and documentation of the exact date of resuming professional activities (Return to Work).
- **Documentation and comparison of complication rates:** Infections, persistent paresthesia, re-operations, nerve injuries, wound healing disorders.

Schedule of Assessments and Follow-Up Timeline:

Time Point	Visit Type & Duration	Assessments / Measures
Before Surgery (T0)	Outpatient visit (approx. 10 min)	Baseline data, questionnaires (SANE, VAS, BCTQ)
2 Weeks (T1)	In person at the center (approx. 10–15 min)	Wound inspection + questionnaires (SANE, VAS, BCTQ)
6 Weeks (T2)	Telephone interview (approx. 10 min)	Questionnaires (SANE, VAS, BCTQ)
3 Months (T3)	Telephone interview (approx. 10 min)	Questionnaires + satisfaction + return to work
12 Months (T4)	Telephone interview (approx. 10 min)	Final evaluation (SANE, VAS, BCTQ)

You are asked to visit your study center once for study purposes, 2 weeks after your surgery. The remaining follow-up appointments will be conducted with you by telephone at the scheduled time points. The time required for each follow-up is approximately 10–15 minutes. In total, your additional time commitment resulting from study participation is approximately 60 minutes over the entire 52-week period.

Adherence to the appointment schedule, including following the instructions of the study physician, is essential for the success of this clinical study.

What is the benefit of participating in the clinical study?

You should not expect to derive any direct personal health benefits from your participation in this clinical study. However, your participation allows an alternative, already routinely performed technique for surgical carpal tunnel release to be scientifically evaluated and compared with the conventional standard procedure. This may lead to procedure adaptations or refinements in future treatments, which could potentially benefit future patient care.

Are there risks, discomforts, and adverse effects?

No additional medical risks arise within the scope of this study, because:

- no study-specific invasive procedures or interventions are performed, and

- all surgical measures strictly correspond to routine clinical standard care.

Participation in the study is limited exclusively to questionnaire assessments and the collection of clinical follow-up data.

Possible discomforts:

- Time commitment required for completing questionnaires
- Minor inconvenience associated with telephone follow-up interviews

Note regarding surgery-related risks:

The surgical procedure itself is not part of the study intervention, but is performed as part of established, routinely applied medical standard care. General surgery-related risks may include (independent of the study):

- Infections
- Wound healing complications
- Pain or scar tenderness
- Sensory disturbances or, rarely, nerve injury

These risks exist independently of whether you choose to participate in the study or not.

Does participation in the clinical study have other effects on lifestyle, and what obligations arise?

Participation in this study has no effects on your daily lifestyle beyond those already associated with the standard surgical procedure being performed.

What should be done if symptoms, adverse effects, and/or complications occur?

Since this study is a purely observational trial, no additional medical interventions are carried out as part of the study protocol. The surgery itself is performed independently of study participation as part of your regular medical treatment.

Should you experience any discomfort, symptoms, or complications following surgery (e.g., severe pain, swelling, sensory deficits, or other abnormalities), the following applies:

- Please contact your operating surgeon or treating center immediately.
- Follow the medical guidance and instructions of your treating physician.
- Inform the study team during follow-up contacts about any symptoms or issues that have occurred.

Your medical care is provided exclusively by your treating medical team, completely independent of study participation.

Insurance

No specific trial insurance is required for you within the scope of this study. The applied surgical procedures are routine, established clinical techniques regularly utilized at your treating institution.

When will participation in the clinical study be terminated prematurely?

You may revoke your consent to participate and withdraw from the clinical study at any time without stating reasons, without incurring any disadvantages for your ongoing or future medical care.

Your study physician will promptly inform you of any new findings that emerge regarding this clinical study that might be material to your decision. On this basis, you may re-evaluate your decision regarding continued participation.

It is also possible that your study physician decides to terminate your participation in the clinical study prematurely without obtaining your prior consent. Reasons for this may include:

- You are unable to comply with the study requirements;
- Your study physician concludes that continued participation in the clinical study is not in your medical interest.

Data Protection

In the course of this clinical study, personal data concerning you will be collected and processed. A fundamental distinction is made between:

- **1. Directly identifiable personal data:** Data by which a person is directly identifiable (e.g., name, date of birth, address, social security number, medical imaging scans...);
- **2. Pseudonymized personal data:** Data from which all information allowing direct identification of the individual has been removed, replaced by a code (e.g., a numeric identification code), or rendered unrecognizable (e.g., in medical images). However, despite these safeguards, unauthorized re-identification cannot be entirely ruled out with absolute mathematical certainty.
- **3. Anonymized data:** Data where any link back to the specific individual is definitively ruled out.

Access to directly identifiable data (see Item 1) is restricted to the Principal Investigator and designated study staff members involved in the clinical study or your medical care. Additionally, authorized representatives of the sponsor (Prim. Priv.-Doz. Dr. Thomas Hausner) who are bound by professional secrecy, as well as representatives of competent domestic and/or foreign health authorities and the responsible Ethics Committee, may inspect these data to the extent necessary and mandated by law to verify the proper conduct of the clinical study. All individuals granted access to these data are strictly subject to applicable national data protection legislation and/or the EU General Data Protection Regulation (GDPR).

The key code linking pseudonymized data to your identifying information is stored exclusively at your local study center.

Any transfer or sharing of data takes place solely in pseudonymized or anonymized form.

For scientific publications, only pseudonymized or aggregated/anonymized data will be used.

Your informed consent constitutes the legal basis for processing your personal data. You may revoke your consent to data collection and processing at any time without giving reasons. Following revocation, no further data will be collected from you. However, data collected prior to the revocation may continue to be processed to the extent required to evaluate the clinical study.

Under the GDPR, you have the fundamental rights of access, rectification, erasure, restriction of processing, data portability, and objection, provided that exercising these rights does not render impossible or seriously impair the scientific objectives of the clinical study, and provided this is not contrary to statutory retention requirements.

The anticipated duration of the clinical study is 2 years. The retention period for storing your data beyond the conclusion or termination of the clinical study is governed by statutory retention regulations.

If you have questions regarding the processing of your data in this study, please first contact your Principal Investigator. They may forward your request to the data protection officers if necessary.

Contact details of Data Protection Officers of participating institutions:

- **Data Protection Officer of UKH Salzburg:** Data Protection Officer of AUVA, Vienna Twin Towers, Wienerbergstraße 11, 1100 Vienna (E-mail: dsb@auva.at, Tel.: +43 5 93 93-21102).
- **Data Protection Officer of the Department of Radiology (University Hospital Salzburg):** Alexandra Graf (E-mail: alexandra.graf@salk.at, Tel.: +43 5 7255 30010).

You have the right to lodge a complaint with the Austrian Data Protection Authority (Österreichische Datenschutzbehörde) regarding the processing of your personal data (Website: www.dsb.gv.at; E-mail: dsb@dsb.gv.at).

Will participants incur any costs? Is there reimbursement or compensation?

No additional costs will arise for you as a result of your participation in this clinical study.

You will not receive any financial remuneration or compensation for participating in this clinical study.

Opportunity to Discuss Further Questions

Your study physician and their research team are at your disposal to answer any questions in connection with this clinical study. Inquiries concerning your rights as a patient and study participant will also be gladly answered at any time.

- **Contact person:** Dr. Alexander Paszicsnyek — Available at: +43 59393 44211
- **Contact person:** Dr. Christoph Knapitsch — Available at: +43 5 7255 54915
- **Contact person:** Dr. Nikolaos Schörghofer — Available at: +43 5 7255 54901

Independent Patient Advocacy Board (Salzburg):

Salzburger Patientenvertretung
Address: Sebastian-Stief-Gasse 2, 5020 Salzburg
Telephone: +43 662 8042 2030
E-mail: patientenvertretung@salzburg.gv.at

Should other treating physicians be informed of study participation?

No. Routine notification of your general practitioner will not take place.

Informed Consent Form

Study: Prospective Multicenter Trial Comparing Open Surgical Decompression versus Minimally Invasive Ultrasound-Guided Carpal Tunnel Release
(Open vs. Ultrasound-Guided Carpal Tunnel Release)

Patient Name: _____ Date of Birth: _____

☒ I hereby agree to participate in the clinical study "Open vs. Ultrasound-Guided Carpal Tunnel Release".

☒ I have been informed that I may decline participation without any adverse consequences, particularly regarding my ongoing medical care.

☒ I have received detailed and comprehensive information from Dr. ..... regarding the clinical study, potential burdens and risks, as well as the nature, significance, scope of the clinical study, and the requirements resulting for me.

☒ In addition, I have read the complete text of this Patient Information and Informed Consent Form. All questions that arose were answered comprehensibly and satisfactorily by the investigator. I had sufficient time to make my decision. I currently have no further questions.

☒ I agree to follow the medical instructions required for the conduct of the clinical study, but reserve the right to withdraw my voluntary participation at any time without incurring any disadvantages, particularly regarding my medical care.

☒ I expressly consent to the processing of my data collected in the context of this clinical study as described in the "Data Protection" section of this document.

☒ I have received a copy of this Patient Information and Informed Consent Form. The original remains with the Principal Investigator.

.....

(Date and Signature of the Patient)

.....

(Date, Name, and Signature of the Responsible Principal Investigator)

(The patient receives a signed copy of the Patient Information and Informed Consent Form; the original remains in the investigator's study master file.)

For reasons of readability, gender-neutral or generic forms may be used in parts of this document. Unless otherwise specified, all terms apply equally to all genders.