SOP 3: Follow-up and Data Collection

Quick Reference Checklist

1. Purpose and Scope

- Follow-up schedule, electronic questionnaires, 6-month visit, adverse events (AEs), unplanned contacts, reoperations, and discontinuation

2. Follow-up Schedule and Electronic Questionnaires

- **Timepoints:** 3, 6, and 12 months post-randomization
- **Process:** REDCap automatically sends questionnaire links (email/text) and up to three reminders every 3 days

3. Six-Month Outpatient Clinic Visit

- **Mandatory:** Physical clinic visit for all participants
- **Assess:** Ganglion presence and sick leave duration (in days) in the REDCap **Ganglion presence and sick leave** instrument
- **Non-operative group:** Offer crossover to operative treatment if difficult symptoms persist
- **Review:** Go over reported adverse events with the patient

4. Adverse Events (AE) Tracking and Reporting

- **Patient reporting:** At 3, 6, and 12 months via REDCap (infection, nerve/tendon injury, CRPS, ROM restriction, or free-text)
- **Investigator action (6 months):** Evaluate causality of reported AEs and assess severity. Review any newly reported AEs after the 12-month questionnaires and contact the patient if necessary to determine causality
- **SAE classification:** Identify serious events (hospitalization, significant disability, life-threatening, death)
- **Ad-hoc logging:** Record any AEs occurring outside standard timepoints using the REDCap **Adverse events** instrument

5. Unplanned Contacts, Reoperations, and Discontinuation

- **Other contact:** Logged by the person receiving the contact (investigator or study nurse) for any non-protocol contacts. If it is an AE, complete the **Adverse events** form instead
- **Reoperation:** Logged primarily by the operating surgeon (or investigator if no REDCap access)
- **Discontinuation of follow-up:** Logged by the investigator. Select the appropriate reason; REDCap automatically disables future reminders

Full Standard Operating Procedure

1. Purpose and Scope

This Standard Operating Procedure (SOP) describes the follow-up schedule, administration of electronic patient questionnaires, the 6-month outpatient clinic visit, the assessment and reporting of adverse events, and the documentation of unplanned contacts, reoperations, and discontinuation of follow-up.

2. Follow-up Schedule and Electronic Questionnaires

- **Timeline:** Follow-up data is collected at 3, 6, and 12 months post-randomization.
- **Administration:** The REDCap system automatically sends a link to the follow-up questionnaires (including PRWHE scores, Global improvement, PASS, EQ VAS, and patient-reported adverse events) to the participants via email or text message, according to their preference.
- **Reminders:** To maximize the response rate, REDCap is programmed to automatically send a reminder to non-responders every 3 days, up to a maximum of three reminders.

3. Six-Month Outpatient Clinic Visit

All study participants must attend a physical outpatient clinic visit at 6 months post-randomization.

- **Clinical Assessment and Data Collection:** The investigator evaluates the presence of the ganglion and records the total duration of sick leave (in days) during this visit using the **Ganglion presence and sick leave** instrument in REDCap.
- **Treatment Evaluation (non-operative group):** The investigator discusses treatment options with patients in the non-operative group. If difficult symptoms persist, the patient is offered the option to cross over to operative treatment.
- **Adverse Events Review:** The investigator reviews any adverse events reported by the patient. Restricted range of motion in the fingers is evaluated clinically if indicated by the patient's reported symptoms.

4. Adverse Events (AE) Tracking and Reporting

- **Patient Reporting:** Patients self-report potential adverse events via the REDCap questionnaires at the 3, 6, and 12-month time points. Prespecified harms systematically assessed include infection, nerve injury (dysesthesia/paraesthesia), tendon injury (inability to move finger/wrist), CRPS (Budapest criteria), and restricted finger range of motion. Non-prespecified harms are collected via a free-text field.
- **Investigator Assessment:** During the 6-month clinic visit, the investigator evaluates whether the patient-reported adverse events are related to the treated condition. At the end of the participant's follow-up (after the 12-month questionnaires), the investigator must review any newly reported adverse events and, if necessary, contact the patient to determine causality. If a causal relationship is established at any time point, the investigator assesses the severity of the event.
- **Serious Adverse Events (SAE):** An adverse event is classified as an SAE if it requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, is life-threatening, or results in death.

- **Ad-hoc Reporting:** The investigator can log adverse events outside the standard time points using the **Adverse events** instrument in REDCap. A separate form is generated for each individual adverse event.

5. Unplanned Contacts, Reoperations, and Discontinuation

- **Other Contact:** Any protocol-outside communication from a participant must be documented in the **Other contact** instrument by the study staff member (investigator or study nurse) who receives the contact. If the contact pertains to an adverse event, the instrument guides the user to complete the **Adverse events** instrument instead.
- **Reoperation:** If a participant undergoes a reoperation, the details must be recorded using the **Reoperation** instrument in REDCap. This entry is primarily the responsibility of the operating surgeon, or the investigator if the surgeon lacks REDCap access. A reoperation does not inherently lead to the discontinuation of follow-up, as the primary trial intervention has already taken place.
- **Discontinuation of Follow-up:** In the event that a participant's follow-up is discontinued, the investigator must complete the **Discontinuation of follow-up** instrument in REDCap and select the corresponding reason. Upon completion, the REDCap system automatically deactivates all subsequent automated questionnaire reminders for the participant.