SOP 1: Patient Screening, Recruitment, and Randomization

Quick Reference Checklist

1. Purpose and Scope

- Screening, consent, and randomization for the GangLion trial

2. Responsibilities

- Investigator screens, consents, and randomizes
- **Crucial:** This investigator must NOT be the patient's operating surgeon

3. Screening Procedure and Eligibility Criteria

- *Include:* Wrist pain in ganglion area, confirmed ganglion diagnosis, >18 years, can complete questionnaires (FI/EN)
- *Exclude:* Pregnant/breastfeeding, other wrist pathology explaining pain, prior wrist surgery, work-related injury, bilateral (volar and dorsal) symptomatic ganglions on the same wrist

4. Informed Consent Process

- **Discuss:** Benign natural course of ganglions, risks/complications (higher in surgery), and risk of recurrence
- **Non-operative group:** Hand use as tolerated, optional needle aspiration, no other treatments for 6 months
- **Operative group:** Surgery within 2 months, bulky dressing for up to 7 days
- **Both groups:** Immediate home exercises (these same instructions serve as the postoperative rehabilitation protocol for the operative group), 6-month clinic visit (crossover option available for non-operative group), REDCap questionnaires at 3, 6, and 12 months
- **Action:** Sign informed consent in duplicate (one for site, one for patient)

5. Documentation and Randomization (REDCap)

- **All evaluated patients:** Fill out the **Screening log** (stop here if ineligible/declines)
- **Consented patients:**
    1. Fill out the **Baseline data**
    2. Open the **Randomization** instrument and click randomize
    3. Patient completes the auto-sent baseline questionnaires (PRWHE, EQ VAS) on a mobile device at the clinic
    4. *(If applicable)* Study nurse receives auto-notification to schedule the 6-month visit

Full Standard Operating Procedure

1. Purpose and Scope
This Standard Operating Procedure (SOP) describes the processes for patient screening, informed consent, and randomization in the "GangLion resection effectiveness trial (GangLion): a multicentre, randomized, superiority trial" at the outpatient clinics.

2. Responsibilities
The designated study investigator is responsible for screening patients, conducting the informed consent process, and entering baseline data into REDCap. To prevent observer bias, the investigator performing these tasks must not be the surgeon who performs the trial surgery for the respective participant.

3. Screening Procedure and Eligibility Criteria
Patients with a suspected wrist ganglion referred to national tertiary and secondary referral centres in Finland and Singapore are directed to the outpatient clinic. The investigator evaluates the patient based on the following criteria:

Inclusion criteria:

1. Wrist pain located in the ganglion area.
2. Diagnosis of ganglion of the wrist, based on clinical examination or imaging findings.
3. Age over 18 years.
4. Ability to fill out the Finnish or English version of the questionnaires.
   (Note: If there is a symptomatic ganglion in both wrists, the more symptomatic wrist is included.)

Exclusion criteria:

1. Pregnant or breastfeeding.
2. Other known wrist pathology that likely explains the pain.
3. Previous surgical treatments of the wrist.
4. Wrist ganglion presumed to be related to a work injury.
5. Symptomatic ganglion at both sides (volar and dorsal) of the wrist.

4. Informed Consent Process
For eligible patients, the investigator conducts a standardized discussion covering the following points:

- **Natural Course & Risks:** Explanation of the benign nature of wrist ganglions, their natural progression, and the risks of both treatment methods. The patient is informed that non-operative management has a lower complication rate, whereas surgery carries a higher risk of complications. The potential for ganglion recurrence after surgery is also mentioned.
- **Non-operative Treatment Group:** Patients are advised that wrist loading in extension may exacerbate pain, but it does not indicate further joint injury. Hand use is allowed as tolerated. NSAIDs and acetaminophen can be used as needed. Needle aspiration may be performed, but it is not a routine requirement. Participants are instructed not to seek other treatments during the 6-month follow-up period.

- **Operative Treatment Group:** Surgery (open or arthroscopic) is performed within 2 months of randomization. A bulky dressing is applied for up to 7 days, after which free use of the hand is allowed. Depending on local site protocols and logistics, the patient may be directed to a clinic nurse for preoperative preparation and surgical scheduling.
- **Follow-up Protocol for Both Groups:** All participants receive self-implemented exercise therapy instructions to begin immediately. For the operative treatment group, these same instructions serve as the required postoperative rehabilitation protocol. Both groups will attend an outpatient clinic visit at 6 months to assess the presence of the ganglion and sick leave duration. Patients in the non-operative group are assured that a 6-month observation period is safe, and they have the option to cross over to operative treatment after this 6-month visit if difficult symptoms persist.
- **Study Questionnaires:** Patients are informed that they will receive links to follow-up questionnaires (assessing functional scores such as PRWHE, global improvement, and adverse events) via email or text message at 3, 6, and 12 months.
- **Consent:** The patient reads the written study information sheet. If willing to participate, the patient signs the informed consent form in duplicate (one copy retained at the study site, one provided to the patient).

5. Baseline Data Collection, Randomization, and Patient Questionnaires

The investigator fills out the **Screening log** instrument in the REDCap system for all evaluated patients, regardless of whether they are eligible or willing to participate. The instrument indicates eligibility, but the final decision remains with the investigator. If a patient is ineligible or declines participation, this is recorded in the Screening log, and the process ends.

For patients who provide written consent, the investigator completes the following additional steps in REDCap:

1. Fills out the **Baseline data** instrument.
2. Opens the **Randomization** instrument. The system automatically applies stratification variables (Location of the ganglion, Study country). The investigator must click the randomization button to allocate the participant to either the non-operative or operative treatment group.
3. Immediately after randomization, the REDCap system automatically sends the baseline questionnaire link to the patient via email or text message, as per the patient's preference. The patient completes the initial questionnaires (e.g., PRWHE, EQ VAS) on a mobile device, such as their own smartphone or a clinic tablet, before leaving the clinic.
4. **Administrative Handover:** Depending on local site protocols, the REDCap system can automatically send a notification email to a designated study nurse. If applicable, the study nurse archives the original signed informed consent forms and schedules the 6-month follow-up outpatient clinic visit.