SOP 2: Surgical Intervention

Quick Reference Checklist

1. Purpose and Scope
- Surgery, postoperative care, and data collection

2. Responsibilities
- Operating surgeon performs surgery and completes REDCap immediately post-op

3. Preoperative Preparation
- **Timing:** Surgery in an operation room within 2 months of randomization
- **Protocols:** Anaesthesia, tourniquet, and prophylaxis per local practice/surgeon preference

4. Surgical Procedure: Open Resection
- Tangential pedicle resection (usually SL ligament for dorsal)

5. Surgical Procedure: Arthroscopic Resection
- Locate and resect pedicle with a shaver. (No need to remove all walls)

6. Postoperative Care
- Bulky dressing applied (patient removes within a week)
- Pain management as needed (NSAIDs/acetaminophen)
- Immediate active range of motion exercises (following the instructions already provided at the baseline recruitment visit)

7. Surgical Data Entry and Outcome Prediction (REDCap)
- **Immediate action:** Complete the **Surgery** instrument in REDCap
- Record operative details (anaesthesia, method, duration, notes)
- Predict 6-month outcomes (PRWHE total, PRWHE pain, global improvement) based on displayed baseline data
- Provide an open-ended explanation of factors influencing the prediction

Full Standard Operating Procedure

1. Purpose and Scope
This Standard Operating Procedure (SOP) describes the standardized procedures for the surgical intervention, postoperative care, and surgical data collection in the "GangLion resection effectiveness trial (GangLion): a multicentre, randomized, superiority trial".

2. Responsibilities
The operating surgeon is responsible for performing the surgery according to the protocol and completing the "Surgery" instrument in the REDCap system immediately after the procedure.

3. Preoperative Preparation
- **Timing and Setting:** The ganglion resection must be performed in an operation room within 2 months of randomization.
- **Anaesthesia and Tourniquet:** There are no strict protocol requirements. Anaesthesia method (e.g., plexus block) and the use of a tourniquet are left to the local clinic's standard practice and the surgeon's preference.
- **Prophylaxis:** Antimicrobial prophylaxis is not routinely required by the protocol and depends on local guidelines.

4. Surgical Procedure: Open Resection
The choice between open or arthroscopic approach is left to the operating surgeon. If an open approach is selected:
1. **Incision:** A transverse or longitudinal incision is made depending on the surgeon's preference.
2. **Resection:** The ganglion and its pedicle are traced up to their origin. The pedicle is resected tangentially. For dorsal ganglions, this is usually from the scapholunate (SL) ligament. For volar ganglions, the resection depends on the specific site.
3. **Capsule:** The wrist capsule must not be closed.

5. Surgical Procedure: Arthroscopic Resection
If an arthroscopic approach is selected:
1. **Portals:** Portals are selected by the surgeon's preference.
2. **Resection:** The pedicle of the ganglion is located and resected with a shaver. It is not necessary to remove all the ganglion walls.
3. **Closure:** The portal incisions do not need to be sutured.

6. Postoperative Care
- **Dressing:** A bulky dressing is applied for the patient's comfort in both treatment methods. The patient is instructed to remove the dressing within a week (e.g., 2–3 days).
- **Pain Management:** Participants may use NSAIDs and acetaminophen for pain management as needed. The protocol does not specify a required course or dosage.
- **Rehabilitation:** Active range of motion exercises must be begun immediately. Patients follow the same simple self-implemented exercise therapy instructions that were already provided to them during the baseline recruitment visit.

7. Surgical Data Entry and Outcome Prediction (REDCap)
Immediately after the procedure, the operating surgeon must complete the **Surgery** instrument in REDCap.

- **Operative Details:** The surgeon records the anaesthesia type, utilized surgical method, duration of the surgery, and any special notes regarding the procedure.
- **Prediction of Recovery:** To evaluate the surgeon's prediction of the treatment effect, the instrument will display the participant's baseline PRWHE pain score, PRWHE total score, and the minimal important change (MIC) values. Based on these, the surgeon must record:
    1. Predicted 6-month PRWHE total score.
    2. Predicted 6-month PRWHE pain score.
    3. Predicted 6-month perceived global improvement on a 7-step Likert scale.
    4. An open-ended explanation of the clinical or patient-specific factors that influenced the prediction.