Name of the Study:

Randomized Control Trial (RCT): Superiority Study for Inter-scalene Block Execution Time in Traumatological Shoulder Surgery and Non-inferiority for Effectiveness between Two Blocking Methods: Catheter Over Needle (CON) vs Catheter Through Needle (CTN).

NCT: Not Assigned yet

Date of last review board: 21/09/2022

Protocol This clinical trial will be registered on www.clinicaltrials.gov. Upon approval from the institutional ethics review committee, the recruitment of 36 patients per group undergoing rotator cuff or proximal humerus surgery, who meet the inclusion criteria, do not have exclusion criteria, and agree to participate in the study, will be conducted. Informed consent will be obtained, and prior randomization generated by a computer program, each patient will be assigned to the allocated group: Catheter Through Needle (CTN) or Catheter Over Needle (CON). The inclusion criteria will be: age over 18 years, ASA I-III, BMI 18-35 kg/m2. Exclusion criteria will be inability to consent to the study, coagulopathy, sepsis, renal or hepatic failure, allergy to local anesthetics, previous peripheral nerve damage, and refusal of the postoperative continuous block technique. Block execution: After the patients arrive at the operating room, an 18 or 20-gauge intravenous Teflon catheter will be placed in the contralateral arm to the operated limb, installed in the preoperative unit by the responsible nurse. Monitors will be set up: continuous 3-lead electrocardiography, non-invasive ankle pressure, and pulse oximetry. After the safety pause, the patient will be premedicated with midazolam 1-4 mg and fentanyl 50-100 mcg. Supplementary oxygen will be administered via a Venturi mask at 4 L/min. With the patient in supine and semisitting position, an ultrasound-guided inter-scalene block image will be obtained (according to the established model for an acceptable injection site) ipsilateral to the surgery, using a linear ultrasound transducer of 6-13 MHz (Sonosite). Then, the area will be aseptically prepared with chlorhexidine, and local anesthesia will be administered with 2% lidocaine, 3-4 ml. Using a plane technique, the Contiplex® C needle set will be used for the CON randomized group, and the Contiplex Touhy™ (CT) set for the CTN group. The time in seconds from the start of the puncture with both catheters until the application of 3M™ Tegaderm™ dressing for fixation will be timed. All blocks will be performed by non-expert residents trained in the use of each needle-catheter set and/or by an expert anesthesiologist (in equal proportion in each group). The number of attempts or punctures will also be measured, defining each attempt as any reinsertion of the needle through the skin once the block has started. After completing the block, the patient will be anesthetized with balanced general anesthesia, using Propofol 1-2 mg/kg as an induction agent, fentanyl 3-5 mcg/kg, neuromuscular relaxation as needed. The airway will be instrumented with a laryngeal mask or endotracheal tube at the anesthesiologist's discretion. Ketorolac and paracetamol will be used as multimodal analgesia unless contraindicated. Dexamethasone IV and/or ondansetron will be used for the prevention of nausea based on classic criteria for preventing postoperative nausea and vomiting. Once the surgery is finished, a home analgesia pump (elastomeric pump) will be connected to the catheter, and the patient will be educated on the outpatient removal of the catheter according to the institutional protocol. Telephone follow-up will be conducted to assess pain, complications, the need for urgent oral analgesia, or accidental catheter removal, filling out the attached form in the annex. Effective block will be classified as pain on the visual analog scale (VAS) equal to or less than 4 out of 10, and accidental removal as displacement of more than 2 cm from the fixation point recorded on the anesthesia sheet. The installation times and effectiveness of both catheter sets will be compared at 24- 48-72 hours.