Study Protocol

Intraoperative Pain During Carpal Tunnel Release: WALANT vs Local Anesthesia and Tourniquet – A Randomized Controlled Trial

1. Administrative information

- **Protocol Version:** 1.0 (Final), dated 10 October 2024.
- **Principal Investigator (PI):**
    - Mohammed Safwat Kamal Hamza, MD, PhD
    - Associate Professor of Orthopedic Surgery
    - Faculty of Medicine, Misr University for Science and Technology, Giza, Egypt
- **Co-Investigators:**
    - Ahmed Adel Ayad, MD, PhD – Assistant Professor of Neurosurgery, Al-Azhar University, Cairo, Egypt
    - Others as per authorship list (Zainab Alobied, Asmaa ElNajjar, Ahmmed Zabbady).
- **Study Sites:**
    - Site 1: Department of Orthopedic Surgery, tertiary university hospital, Giza, Egypt.
    - Site 2: Department of Neurosurgery, tertiary university hospital, Cairo, Egypt.
- **Regulatory / Ethics Approvals:**
    - Approved by institutional review board/ethics committee at participating centers prior to enrollment.
    - Conducted according to the Declaration of Helsinki and CONSORT 2025 RCT reporting guidance.
- **Funding:**
    - No external funding.

2. Background and rationale

Carpal tunnel decompression (CTD) is one of the most common hand procedures, with several anesthetic options including local anesthesia with pneumatic tourniquet (LA-T), regional block, and general anesthesia. Tourniquet use can cause significant pain, anxiety, and potential complications without proven long-term functional benefit.

Wide-awake local anesthesia no tourniquet (WALANT) uses lidocaine with epinephrine to achieve field anesthesia and vasoconstriction, avoiding tourniquet and sedation, while allowing intraoperative functional assessment and potentially reducing costs and turnaround time. Prior RCTs and observational studies suggest lower perioperative pain and similar complication rates with WALANT, but many are limited by small sample size, non-blinded designs, and single-surgeon experience.

This trial was designed as a multicenter, prospective, double-blinded randomized controlled study to provide high-quality evidence comparing WALANT versus LA-T for intraoperative pain and related outcomes in CTD.

3. Objectives and hypotheses

Primary Objective
To compare intraoperative pain during open carpal tunnel decompression performed under WALANT versus LA-T in adult patients with carpal tunnel syndrome.

Secondary Objectives

- To compare pain during local anesthetic infiltration between WALANT and LA-T.
- To assess tourniquet-specific pain in the LA-T group.
- To compare operative time between groups.

- To compare patient satisfaction with the operating-room experience.
- To describe intraoperative complications in each group.

Primary Hypothesis
WALANT will result in significantly lower overall intraoperative pain (VAS) than LA-T.

Secondary Hypotheses

- Infiltration pain will be similar between WALANT and LA-T.
- Tourniquet pain will contribute to higher intraoperative pain in LA-T.
- WALANT will shorten operative time compared with LA-T.
- Patient satisfaction will be high and not inferior in WALANT compared with LA-T.

4. Study design

Prospective, multicenter, double-blinded, randomized controlled trial with two parallel arms (1:1 allocation). Patients were randomized to WALANT or LA-T and followed through the perioperative period until early postoperative assessment.

- **Study Type:** Interventional, treatment.
- **Interventional Model:** Parallel assignment, two arms.
- **Masking:**
    - Patients and outcome assessors: blinded to group allocation.
    - Surgeons and anesthetic personnel: aware of technique for safety; allocation concealed until after consent and randomization.

5. Study setting and timeline

- **Sites:**
    - Tertiary academic orthopedic and neurosurgical departments in Giza and Cairo, Egypt.
- **Study Period:**
    - Enrollment and follow-up from December 2024 to December 2025.

6. Eligibility criteria

Inclusion Criteria

- Age ≥18 years.
- Clinical diagnosis of carpal tunnel syndrome confirmed by nerve conduction and electromyographic studies.
- Candidate for surgical treatment with open carpal tunnel decompression.
- American Society of Anesthesiologists (ASA) physical status I or II.
- Ability to provide written informed consent.

Exclusion Criteria

- Surgery-related anxiety requiring sedation or general anesthesia.
- Known contraindication or allergy to lidocaine or epinephrine.

- Active local or systemic infection at the surgical site.
- ASA physical status III or higher.
- Pregnancy or breastfeeding.
- Inability to understand or complete pain and satisfaction scales, or to provide informed consent.

7. Interventions

Arm A – WALANT

- 20 mL of 1% lidocaine (200 mg) with epinephrine 1:100,000, buffered with 8.4% sodium bicarbonate (10:1 ratio).
- Infiltrated into the operative field approximately 20 minutes before incision in a preoperative area.
- No tourniquet used.
- Mini-open carpal tunnel release through a 2–3 cm incision in a minor procedure room, under full aseptic technique; hemostasis via epinephrine-induced vasoconstriction and meticulous technique.

Arm B – Local Anesthesia With Tourniquet (LA-T)

- 20 mL of 1% lidocaine (200 mg) buffered identically but without epinephrine.
- Infiltrated approximately 5 minutes before incision in the operating room.
- A blood-pressure cuff tourniquet placed above the elbow (no exsanguination), inflated to 100 mmHg above systolic pressure after arm elevation and draping, released after skin closure.
- Mini-open carpal tunnel release through a 2–3 cm incision under standard aseptic conditions.

Two experienced surgeons (orthopedic hand consultant and neurosurgery peripheral nerve specialist) performed all procedures; each performed approximately 50 cases.

8. Outcomes

Primary Outcome

- Overall intraoperative pain (VAS 0–10): patient's rating of pain during the entire surgery, assessed immediately after surgery by a blinded assessor.

Secondary Outcomes

- Infiltration pain (VAS 0–10): pain during local anesthetic injection.
- Tourniquet pain (VAS 0–10): tourniquet-specific pain in LA-T group.
- Operative time (minutes): from skin incision to completion of skin closure.
- Patient satisfaction (0–10 scale): global satisfaction with the operating-room experience.
- Intraoperative complications: bleeding requiring intervention, nerve injury, or other deviations from normal course.

Demographics: age, sex, BMI, ASA class, CTS-6 severity score.

9. Sample size

A target sample of 100 patients (50 per arm) was chosen based on feasibility at the two centers and expected medium effect size in intraoperative pain VAS. Post-hoc analysis showed that with 50 participants per group and the observed

effect size (Cohen's d ≈ 0.75), power was approximately 94% (two-sided α = 0.05) to detect the group difference in intraoperative pain.

10. Randomization and allocation concealment

- Simple computerized randomization with 1:1 allocation to WALANT or LA-T.
- Randomization list held by an investigator (Z.A.) not involved in surgery or postoperative assessment.
- On the day of surgery, the investigator informed the operating surgeon of the assigned technique after consent, maintaining concealment before enrollment.

11. Blinding

- Patients were not explicitly told which anesthetic technique they received.
- Outcome assessors (who collected VAS and satisfaction scores) were independent and blinded to group assignment.
- Surgical team necessarily aware of technique; however, standardized perioperative communication and identical questionnaires minimized performance bias.

12. Data collection and management

- Standardized questionnaire completed postoperatively by the patient and a blinded assessor captured VAS scores, satisfaction, and complications.
- Operative time and tourniquet parameters abstracted from operative notes.
- Data were entered into a secure, password-protected electronic spreadsheet; quality checks performed for range and consistency.

13. Statistical considerations

See separate SAP (Section B). Briefly, continuous variables were summarized as mean ± SD or median (IQR) depending on distribution; categorical variables as counts and percentages. Intraoperative VAS (primary outcome) was compared using Mann–Whitney U test; subgroup analyses by age, sex, and surgeon were pre-specified.

14. Ethical considerations

- Approved by IRB/ethics committee at participating institutions.
- All participants provided written informed consent before randomization.
- Risks: injection pain, tourniquet discomfort (LA-T), bleeding, infection, nerve injury, allergic reaction, cardiovascular effects of epinephrine; these are standard risks of hand surgery and local anesthesia.
- Benefits: potential for improved intraoperative comfort; contribution to knowledge that may improve anesthetic choices for future patients.
- Confidentiality: data stored with coded IDs; no identifying information in reports or publications.

B. Statistical Analysis Plan (SAP)

Study: WALANT vs Local Anesthesia With Tourniquet for Carpal Tunnel Decompression – Randomized Controlled Trial

1. Objectives and endpoints

Primary Endpoint

- Overall intraoperative pain VAS (0–10).

Secondary Endpoints

- Pain during anesthetic infiltration (VAS 0–10).
- Tourniquet pain in LA-T group (VAS 0–10).
- Operative time (minutes).
- Patient satisfaction score (0–10).
- Intraoperative complications (yes/no; type).

2. Analysis populations

- **Intention-to-Treat (ITT) Population:**
  All randomized participants analyzed according to allocated group, regardless of minor protocol deviations, provided primary outcome data are available.
- **Per-Protocol (PP) Population (exploratory):**
  Subset excluding major deviations (e.g., cross-over of anesthetic technique, incomplete surgery) if any occurred. Primary inferences will be based on ITT; PP will be supportive.

3. General statistical principles

- Two-sided tests with significance level $\alpha = 0.05$.
- Continuous variables: reported as mean ± SD if approximately normal, or median (IQR) if skewed.
- Categorical variables: counts and percentages with 95% confidence intervals.
- Normality checked with Shapiro–Wilk test and inspection of histograms.
- Main analyses non-parametric where distribution assumptions are not met; parametric tests may be reported as sensitivity analyses.
- Statistical software: SPSS version 29.

4. Baseline characteristics

Baseline demographics and clinical characteristics (age, sex, BMI, ASA class, CTS-6 score) will be summarized by group using descriptive statistics.

- Continuous variables: compared using independent-samples t-test or Mann–Whitney U test as appropriate.
- Categorical variables: compared using chi-square or Fisher's exact test as appropriate.
  These comparisons are descriptive; no p-value adjustment is planned as they are not hypothesis-driven.

5. Primary outcome analysis

Outcome: Overall intraoperative pain VAS (0–10).

- **Primary analysis method:**
  Mann–Whitney U test comparing VAS scores between WALANT and LA-T.
- Effect size:
  - Median difference with 95% CI.
  - Non-parametric effect size measure (e.g., rank-biserial correlation) as reported; you previously used effect size ≈0.63 with 95% CI.

- **Sensitivity analysis:**
  Independent-samples t-test (parametric), assuming approximate normality, to corroborate non-parametric findings.

No adjustment for multiple testing is applied to the primary endpoint.

6. Secondary outcomes analysis

1. **Infiltration pain VAS (0–10)**
    - Analysis: Mann–Whitney U test comparing WALANT vs LA-T.
    - Report: medians (IQR), means (SD), p-value, and effect size.
2. **Tourniquet pain VAS (LA-T only)**
    - Descriptive analysis within LA-T arm: median (IQR), distribution plots.
    - No between-group statistical test (not defined in WALANT arm).
3. **Operative time (minutes)**
    - Analysis: Mann–Whitney U test for group comparison.
    - Report: median (IQR) per group, p-value, effect size.
4. **Patient satisfaction (0–10)**
    - Analysis: Mann–Whitney U test to compare satisfaction scores between groups.
    - Report: median (IQR), p-value, and effect size.
5. **Intraoperative complications**
    - Analysis: counts and proportions in each group; Fisher's exact or chi-square test if sufficient events.
    - Given low expected event counts, analysis is primarily descriptive.

Multiplicity:
Secondary outcomes are interpreted cautiously; no formal adjustment for multiple comparisons. Emphasis remains on the primary outcome.

7. Subgroup analyses

Pre-specified subgroups:

- Age group: <65 vs ≥65 years.
- Sex: male vs female.
- Surgeon: Orthopedic (Surgeon A) vs Neurosurgery (Surgeon B).

For each subgroup:

- Compare intraoperative VAS between WALANT and LA-T using Mann–Whitney U test within strata.
- Test for interaction (e.g., using non-parametric interaction tests or rank-based methods) to assess whether the treatment effect differs by age, sex, or surgeon; manuscript reported non-significant interactions (age p=0.45, sex p=0.82, specialty p=0.76).

Subgroup findings are exploratory and hypothesis-generating.

8. Handling of missing data

- Missing primary outcome data are expected to be rare because VAS is collected immediately postoperatively.
- If isolated missing VAS values occur, primary analysis will be complete-case (excluding those without any intraoperative VAS value). Given small numbers, imputation is unlikely to materially change results.
- If >5% of participants lack primary outcome data, a sensitivity analysis using simple imputation (e.g., median of group) may be explored, but the main report will transparently present complete-case results.

9. Sensitivity and additional analyses

- **Timing of anesthetic administration:**
  Exploratory analyses to assess whether variation in injection-to-incision time confounds results; previous sensitivity analysis showed no meaningful pattern.
- **Post-hoc power:**
  Based on observed effect (mean 0.80 vs 2.08, pooled SD 1.52), Cohen's d ≈ 0.75, and n=50 per group, post-hoc power ≈94% (α=0.05).
- **Graphical displays:**
  Box plots and distribution plots for VAS scores, operative time, and tourniquet pain; subgroup plots by age, sex, and surgeon.

C. Informed Consent Form (ICF – Patient Version)

Title of Study:
Intraoperative Pain During Carpal Tunnel Release: WALANT vs Local Anesthesia and Tourniquet – A Randomized Controlled Trial

Principal Investigator:
Dr. Mohammed Safwat Kamal Hamza, MD, PhD
Faculty of Medicine, Misr University for Science and Technology, Giza, Egypt

Study Doctors:
Dr. Mohammed Hamza (Orthopedic Surgery), Dr. Ahmed Adel Ayad (Neurosurgery), and team.

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1. Introduction and invitation

You are being invited to take part in a research study because you have carpal tunnel syndrome and your doctor has recommended surgery (carpal tunnel decompression). Please read this information carefully and ask any questions you may have before deciding whether to participate.

Participation is completely voluntary.

2. Purpose of the study

The purpose of this study is to compare two ways of giving local anesthesia for carpal tunnel surgery:

- **WALANT**: "Wide-Awake Local Anesthesia No Tourniquet" – local anesthetic with a small amount of adrenaline (epinephrine) injected in the hand, without using a tourniquet and usually without sedation.
- **Local anesthesia with tourniquet (LA-T)**: local anesthetic injected without adrenaline while a blood pressure cuff (tourniquet) is placed on the arm during surgery.

We want to see which method gives better pain control during surgery, and how they affect patient satisfaction and operative time.

3. Why have I been invited?

You are an adult patient (18 years or older) with carpal tunnel syndrome confirmed by clinical examination and nerve tests, and you are scheduled for open carpal tunnel decompression at one of our participating hospitals.

4. Do I have to take part?

No. Your participation is entirely voluntary. If you decide not to take part, or to withdraw later, your usual care will not be affected in any way.

If you withdraw after joining, any information collected until that point may still be used in the study in a confidential way.

5. What will happen if I take part?

If you agree to participate and sign this form:

1. You will have a brief examination and review of your medical history to confirm that you meet the study criteria (for example, your general health and medications).
2. You will be randomly assigned (like a coin toss) to one of two groups:
    - WALANT (local anesthetic with adrenaline, no tourniquet), or
    - Local anesthesia with tourniquet (no adrenaline).
3. You will then undergo your planned open carpal tunnel surgery as usual. The only difference from standard care is which of these two local anesthesia methods is used.
4. During and after surgery, you will be asked to rate your pain and satisfaction using simple scales from 0 to 10. A member of the study team who is not involved in your surgery will ask you these questions.
5. We will record your operative time and any complications that may occur during the procedure.

Your total participation is limited to the surgery day and a short period afterwards to collect data; no extra clinic visits are required beyond routine care.

6. Description of the study procedures

If you are in the WALANT group:

- You will receive injections of local anesthetic with a small dose of adrenaline into the area of your hand where the surgery will be performed.
- The injection will be given about 20 minutes before the operation to allow full effect.
- No tourniquet will be used on your arm.
- You will be awake during surgery but should not feel sharp pain in the surgical area.

If you are in the LA-T group:

- You will receive injections of local anesthetic without adrenaline in the area of your hand.
- The injection will be given about 5 minutes before surgery.
- A blood pressure cuff (tourniquet) will be placed around your upper arm and inflated during the surgery, then deflated at the end.
- You will also be awake during surgery.

In both groups, if you feel unacceptable pain, the surgical team will provide additional local anesthetic, adjust the tourniquet (if present). Your safety and comfort are always the priority.

7. How long will I be in the study?

Your involvement is limited to your operation day and immediate postoperative period. We may review your hospital records up to 30 days after surgery to record any complications related to the procedure.

8. What are the possible risks and discomforts?

All medical procedures and anesthetic techniques involve some risk. Risks in this study are similar to usual care and include:

- Pain or discomfort during the local anesthetic injection.
- Pain or pressure during surgery, especially if the anesthesia is not perfect; this will be treated promptly.
- With LA-T: discomfort or pain from the tourniquet on the arm (tight cuff feeling).
- Bruising or bleeding at the injection or surgical site.
- Infection or poor wound healing (rare).
- Nerve injury or persistent numbness (rare).
- Allergic reaction to the local anesthetic or adrenaline (rare).
- Changes in heart rate or blood pressure, especially in people with heart problems (rare).

If any complication occurs, it will be handled according to standard medical practice.

9. Are there benefits to taking part?

You may or may not benefit directly. You will receive standard surgical treatment for carpal tunnel syndrome regardless of group. Possible benefits include better intraoperative comfort or a quicker procedure, but this cannot be guaranteed.

The information obtained may help doctors choose the best anesthetic technique for future patients with carpal tunnel syndrome.

10. Are there alternatives to participating?

Yes. You can choose not to participate in the study and still have your surgery under any anesthetic technique you and your doctor consider appropriate (for example, local anesthesia with or without tourniquet, regional block, or general anesthesia, depending on local practice).

11. Confidentiality

Your identity will be kept confidential. You will be assigned a study ID number. Data collected for the study (such as pain scores and operative details) will be stored securely and analyzed without your name or direct identifiers.

Only the research team, your treating doctors, and if required, regulatory or ethics committees will be able to see your identifiable medical information. Any reports or publications will not identify you personally.

12. Costs and payment

There is no extra cost to you for participating in this study beyond your usual medical care. You will not receive payment for taking part.

13. What happens if I am injured?

If you suffer harm as a direct result of participating in this research, you will receive appropriate medical care. There is no separate research insurance or financial compensation beyond standard hospital policies.

14. Voluntary participation and right to withdraw

Your participation is voluntary. You may refuse to participate or withdraw at any time without any effect on your current or future medical care.

If you withdraw, previously collected data may still be used in analysis in a de-identified form.

15. Contact information

If you have questions about the study or a research-related injury, please contact:

- Dr. Mohammed Safwat Kamal Hamza
  Misr University for Science and Technology, Giza, Egypt
  Tel: +20 128 595 8583
  Email: mshamza@must.edu.eg

If you have questions about your rights as a research participant, you may contact the Institutional Review Board/Ethics Committee at your hospital (contact details to be inserted according to local policy).

16. Consent

Please read the statements below. If you agree, sign and date this form.

Participant Statement

- I have read and understood the information in this form.
- I have had the opportunity to ask questions and have received satisfactory answers.
- I understand that my participation is voluntary and that I may withdraw at any time without affecting my medical care.
- I understand that my data will be kept confidential.
- By signing below, I agree to take part in this study.

Participant's Name:

Signature:

Date: _

Person obtaining consent

I have explained the study to the participant and answered all questions.

Name:

Role: _

Signature:

Date: _