# INFORMED CONSENT FORM

**Effects of Preoperative Stellate Ganglion Block and Intraoperative Dexmedetomidine on Postoperative Sleep Quality in Patients Undergoing Laparoscopic Gynecologic Surgery: A Randomized, Controlled, 2×2 Factorial Trial**

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# Effect of Preoperative Stellate Ganglion Block Combined with Intraoperative Dexmedetomidine Infusion on Postoperative Sleep Quality in Patients Undergoing Laparoscopic Gynecologic Surgery
# Informed Consent Form

Dear Patient:

You are invited to participate in a clinical study investigating the effect of preoperative stellate ganglion block combined with intraoperative dexmedetomidine infusion on postoperative sleep quality in patients undergoing laparoscopic gynecologic surgery. This informed consent form provides information about the study to help you decide whether to participate. Please read it carefully. If you have any questions, you may consult the investigator responsible for the study at any time. Your participation is entirely voluntary. You may decline to participate or withdraw at any time without affecting the routine medical care you receive.

## I. Study Background

In gynecologic surgery, laparoscopic hysterectomy is a commonly used surgical approach for conditions such as uterine fibroids, abnormal uterine bleeding, and endometriosis. Postoperative sleep disturbance is a common complication following such procedures and may adversely affect patients' mood, physical vitality, and postoperative recovery.

Stellate ganglion block (SGB) can modulate sympathetic tone and may improve postoperative sleep and pain. Dexmedetomidine (DEX) is a highly selective $\alpha_2$ -adrenergic receptor agonist with sedative, analgesic, and sleep-architecture-modulating effects. Evidence regarding the combined use of these two interventions to improve postoperative sleep in patients undergoing laparoscopic hysterectomy remains limited. This study therefore aims to explore a safe and effective perioperative strategy for optimizing sleep and facilitating postoperative recovery.

## II. Study Objectives

This study aims to investigate the effect of preoperative stellate ganglion block combined with intraoperative dexmedetomidine infusion on postoperative sleep quality in patients undergoing laparoscopic gynecologic surgery. It will also evaluate the effects of this approach on postoperative pain, speed of recovery, length of hospital stay, and patient satisfaction, with the aim of identifying an efficient, safe, economical, and broadly applicable perioperative intervention.

## III. Study Procedures

If you agree to participate, a study record will be created for you, and you will be asked to complete the relevant preoperative and postoperative assessments and data collection.

### 1. Eligibility and Group Allocation

1.1 Inclusion criteria: American Society of Anesthesiologists (ASA) physical status I-III; age 18-75 years; and scheduled for elective laparoscopic gynecologic surgery.

1.2 Exclusion criteria: preoperative sore throat or hoarseness; upper respiratory tract infection within the preceding 2 weeks; anticipated difficult airway; severe cardiac, hepatic, renal, or other organ dysfunction; allergy to local anesthetics; coagulation abnormalities; infection at the puncture site; or cognitive, psychiatric, or communication impairment, among others.

1.3 Group allocation: Using a random-number table, you will be randomly assigned to one of four groups, with 25 participants in each group. The allocation is random, and neither you nor the outcome assessors will know your specific group assignment:

① SGB + normal saline group: preoperative stellate ganglion block + intraoperative normal saline infusion

② SGB + dexmedetomidine group: preoperative stellate ganglion block + intraoperative dexmedetomidine infusion

③ Sham block + dexmedetomidine group: preoperative sham block (ultrasound probe placement only at the C6 cervical level, with no local anesthetic injection) + intraoperative dexmedetomidine infusion

④ Control group: preoperative sham block + intraoperative normal saline infusion

**2. Interventions**

2.1 Stellate ganglion block/sham block: The procedure will be performed under ultrasound guidance by an experienced anesthesiologist. Participants in the block groups will receive 0.5% ropivacaine, whereas in the sham-block groups only the ultrasound probe will be positioned at the C6 cervical level.

2.2 Intraoperative medication: After induction of general anesthesia, dexmedetomidine will be continuously infused intravenously at 0.2-0.4 $\mu g \cdot kg^{-1} \cdot h^{-1}$ in the dexmedetomidine groups; the control groups will receive an equal volume of normal saline.

2.3 Anesthesia and postoperative analgesia: A standardized general anesthesia protocol will be used, and postoperative analgesia will be provided using a patient-controlled intravenous analgesia (PCIA) pump.

**3. Observations and Assessments**

The following parameters will be recorded at the specified time points:

3.1 Sleep quality: the Pittsburgh Sleep Quality Index (PSQI) on the night before surgery; on postoperative days 1-2, the St. Mary's Hospital Sleep Questionnaire (SMHSQ) and objective sleep data from a Fitbit wearable device, including total sleep time, sleep efficiency, sleep onset latency, and wake after sleep onset.

3.2 Pain assessment: resting visual analog scale (VAS) pain scores at 6, 24, and 48 hours after surgery, analgesic consumption, and the number of patient-controlled analgesia (PCA) button presses.

3.3 Recovery indicators: time to first postoperative ambulation, time to first passage of flatus, and length of hospital stay.

3.4 Satisfaction: the 15-item Quality of Recovery (QoR-15) score at 24 hours after surgery.

3.5 Safety: adverse events such as Horner syndrome, nausea and vomiting, dizziness, and hypotension will be recorded.

## IV. Risks and Discomforts

1. Stellate ganglion block may cause transient Horner syndrome (miosis, ptosis, and conjunctival hyperemia), which usually resolves spontaneously. Serious complications such as vascular injury, hoarseness, and local anesthetic toxicity are rare.

2. Dexmedetomidine may cause transient hypotension, bradycardia, and dry mouth. Vital signs will be closely monitored during surgery, and any such events will be treated promptly.

3. Mild pain, redness, or swelling may occur at the puncture site and usually resolves within a short period.

If you experience any discomfort during the study, regardless of whether it is related to the study, the medical team will promptly evaluate your condition and provide appropriate medical care.

## V. Participant Responsibilities

1. Provide truthful information about your medical history, allergy history, current health status, and medications.
2. Promptly report any discomfort or abnormal reactions that occur during the study.
3. Cooperate with all required preoperative and postoperative assessments and data collection.
4. Do not use medications outside the study protocol that may affect sleep or pain without authorization.

## VI. Privacy and Confidentiality

If you decide to participate in this study, your participation and personal information collected during the study will be kept confidential. Information that could identify you will not be disclosed to anyone outside the research team without your permission. All study personnel and the study sponsor are required to protect your identity. Your records will be stored in locked filing cabinets and will be accessible only to research personnel. To ensure that the study is conducted in accordance with applicable requirements, authorized members of government regulatory authorities or the ethics review committee may, when necessary and in accordance with relevant regulations, inspect your personal information at the study site. No personally identifying information will be disclosed when the results of this study are published.

In addition to this study, your medical records and blood specimens may be reused in future research. You may state now that you do not consent to the use of your medical records and pathological specimens in research other than this study.

## VII. Participant Rights

If you are injured as a result of participating in this study, you may receive free medical treatment and/or appropriate compensation for injury related to this clinical study. You may choose not to participate, or you may notify the investigator at any time that you wish to withdraw from the study. Your data will not be included in the study results, and your medical treatment and rights will not be affected. The study physician may terminate your participation if you require other treatment, if you do not comply with the study plan, if a study-related injury occurs, or for any other reason. You may obtain information about the study and its progress at any time. If you have questions about the study, experience any discomfort or injury during the study, or have concerns regarding your rights as a study participant, you may contact the investigator at any time.

Patient or Legally Authorized Representative: _____

Study Physician: _____

Date of Signature: _____