Informed Consent Form for Participants

Project Title: A Comparison of Laser-Assisted T-mode Ultrasound and Conventional Ultrasound in Adult Central Venous Catheterisation: A Randomised Clinical Trial

Protocol Version Number and Date: Version 4.0, Date: 30 August 2025

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Dear Patient,

We invite you to participate in the study entitled'In-plane versus Real-time bi-plane Single-operator Laser-assisted with a innovative T-shaped probe for ultrasound-guided internal jugular vein catheterization: A Randomized Clinical Trial', which has been approved for conduct at the First Hospital of Jilin University. This study will be conducted at the First Hospital of Jilin University, with an anticipated 352 participants. The study has been reviewed and approved by the Ethics Committee of the First Hospital of Jilin University.

This information sheet is provided to assist you in deciding whether to participate in this clinical trial. Participation is entirely voluntary, and your decision will not affect your rights to standard medical care or treatment at our hospital; please rest assured. Should you choose to participate, our research team will do our utmost to ensure your safety and protect your rights throughout the study.

Please read this information sheet carefully. If you have any questions, please ask the researcher responsible for explaining the informed consent form to you.

1. Background

Central venous catheterisation (CVC) is a common clinical procedure for deep vein access and constitutes one of the essential skills for every clinician. Common sites for catheterisation include the internal jugular vein, subclavian vein and femoral vein; however, the internal jugular vein is the site of choice due to its superficial location, relatively fixed anatomical position, minimal influence from respiratory movement, and low overall complication rate. CVCs have a wide range of applications and are frequently used for rapid blood and fluid transfusions, the administration of highly irritating drugs, and intraoperative haemodynamic monitoring.

CVC insertion is an invasive procedure involving complex techniques; its success requires not only precise vascular localisation but also the smooth insertion of the guidewire and catheter. Failure to do so may result in a range of complications, such as arterial or venous injury, nerve damage, pneumothorax, chylothorax, arrhythmia, cardiac tamponade, and even death. In order to ensure success and safety, minimise puncture-related injury and reduce the incidence of complications, CVC insertion techniques are constantly being refined. Currently, the mainstream CVC insertion methods include traditional anatomical landmark-guided techniques, ultrasound-localisation techniques, and ultrasound-guided techniques. The traditional anatomical landmark-guided method involves blind insertion based on palpation of arterial pulsations, requiring the operator to possess extensive experience in blind insertion. When anatomical structures are abnormal, this method increases the difficulty of insertion, as well as the incidence of complications and failure rates; The ultrasound localisation method involves using ultrasound to scan the target vein prior to puncture, marking the superficial projection of the vein to guide the puncture site. This method allows for the identification of anatomical variations in advance and increases the accuracy of vein localisation; however, if the vein shifts during the procedure, the superficial landmarks will also change, making it impossible to guarantee a successful puncture. In 1986, Yonei et al. first described ultrasound-guided central venous catheterisation; this technique has since been extensively studied and applied in various clinical settings. The traditional ultrasound guidance method employs the short-axis off-axis technique, wherein the long axis of the ultrasound probe is positioned perpendicular to the long axis of the internal jugular vein, projecting a transverse section of the vein onto the centre of the ultrasound image. The vein appears as a circular structure on the image and can be compressed with slight pressure. The puncture needle is inserted at an angle of 30–45° relative to the point of skin contact at the midpoint of the ultrasound probe’s long axis; the needle appears as a hyperechoic structure on the ultrasound image. Under ultrasound guidance, the target vessel is approached and punctured; once blood flow is established, a guidewire is inserted, followed by the venous catheter. This method significantly improves the success rate of first-attempt CVC placement and reduces the incidence of associated complications. In 2002, the National Institute for Clinical Excellence (NICE) recommended that ultrasound-guided central venous catheterisation should be the method of choice for establishing central venous access in both adults and children.

Azmat et al. randomised 200 patients into an ultrasound-guided group and a surface landmark group; the time taken to access a vein was significantly shorter in the real-time ultrasound-guided group than in the surface landmark group [(34.95 ± 11.47) s vs (146.59 ± 40.20) s], and the first-attempt success rate was also significantly higher than in the control group (99% vs 89%). Furthermore, the incidence of carotid artery puncture (9% vs 1%) and haematoma formation (7% vs 0%) was higher in the surface landmark group than in the ultrasound-guided group. The meta-analysis conducted by Wu et al. included 26 randomised controlled trials (RCTs) involving 4,185 patients (2,081 receiving ultrasound guidance and 2,104 receiving surface landmark guidance). The results showed that the failure rate of catheter placement was reduced by 82% in the ultrasound-guided group, and the incidence of mechanical complications such as arterial puncture, haematoma, pneumothorax and haemothorax was also significantly reduced. Furthermore, many similar studies have demonstrated that the use of ultrasound guidance leads to comparable improvements in the success rate of central venous catheterisation and the incidence of complications, as well as corresponding improvements in the time taken for the needle to enter the vein and the number of puncture attempts.

The key difference between T-mode ultrasound and conventional ultrasound methods lies in the probe. Conventional ultrasound probes are transverse-view probes; during puncture, the short-axis out-of-plane puncture method is commonly used, which can only display transverse ultrasound images of the vein and cannot visualise the guidewire or catheter as they enter the vessel; The T-probe is an ultrasound method that combines short-axis and long-axis views. It allows for venous puncture guidance in the short-axis plane and the placement of guidewires and catheters in the long-axis plane, thereby maximising visualisation during the procedure and reducing the risk of complications associated with guidewire and catheter placement.

2. Aims of the Study

To compare the success rates and safety of central venous catheterisation under T-mode ultrasound guidance versus conventional ultrasound guidance.

3. Study Population

Inclusion criteria: Patients must fully understand the benefits and risks of the study, voluntarily agree to participate, and sign an informed consent form; surgical patients requiring central venous catheterisation; ASA classification of Class I–IV; aged 18 years or older.

Exclusion Criteria: Congenital abnormalities of the internal jugular vein; infection, wounds or haematomas near the puncture site; history of surgery on the right side of the neck; patients who have undergone internal jugular vein catheterisation within the past month; patients with neck immobilisation due to surgery or injury.

Withdrawal Criteria: Patients who voluntarily withdraw from the study or are lost to follow-up; other circumstances deemed by the investigator to warrant withdrawal from the study.

4. Study Procedure

Upon arrival in the operating theatre, the patient's sternoclavicular distance (the distance in centimetres from the tip of the chin to the upper margin of the manubrium of the sternum, measured whilst the patient tilts their head back as far as possible) and neck circumference (the circumference at the narrowest point of the neck, measured from the upper margin of the seventh cervical vertebra to the level just below the larynx, in centimetres) were measured and recorded. The patient was placed in the supine position, a peripheral vein was accessed, and routine monitoring of electrocardiogram (ECG), blood pressure, pulse oximetry, end-tidal carbon dioxide ($PETCO_2$) and Bispectral Index (BIS) was initiated. All patients underwent the following anaesthetic induction protocol: intravenous administration of remazolam 5 mg, sufentanil 0.3 μg/kg, propofol 2.5 mg/kg, and rocuronium bromide 0.6 mg/kg. Once the muscle relaxants had taken full effect, a standard-sized endotracheal tube was inserted via video laryngoscopy. Following successful intubation, the patient was connected to the anaesthesia machine. The tidal volume (Vt) was set to 6 ml/kg, positive end-expiratory pressure (PEEP) to 5 cmH_2O, inspired oxygen concentration (FiO_2) to 60%, and the inspiratory-to-expiratory ratio (I:E) to 1:2. The respiratory rate (RR) was adjusted to maintain $PETCO_2$ between 35 and 45 mmHg. Inhaled sevoflurane at 1 MAC, with continuous intravenous infusion of propofol at 0.6–1.2 mg/(kg·h) and remifentanil at 0.02–0.15 μg/(kg·h) to maintain a BIS score of 40–60. During anaesthesia, vital signs were maintained at ±20% of baseline levels according to the anaesthetist's judgement, with intermittent bolus doses of rocuronium bromide at 0.15 mg/kg administered as required during the procedure.

Following general anaesthesia and endotracheal intubation, all patients were positioned in a 15° head-down Trendelenburg position, a thin pad is placed under the right shoulder to tilt the head 30° to the left and slightly extend the neck, fully exposing the puncture site. An ultrasound probe is gently placed against the skin without applying downward pressure to scan for the maximum transverse section of the

right internal jugular vein; a mark is made at this point using a sterile marker pen, and the anteroposterior diameter, depth, and carotid artery coverage of the internal jugular vein are measured and recorded. Select a disposable central venous puncture kit for adults (Guangdong Baihe Medical Technology Co., Ltd., dual-lumen 7Fr-20cm). The operator should perform hand hygiene, don sterile gloves, then disinfect the patient's skin and drape the area with a sterile drape. Select the appropriate ultrasound system and probe according to the group allocation (T-shaped probe group and 'long-axis in-plane' group).

The Single-operator Laser-assisted T-shaped probe group：

The research assistant applies appropriate amount of coupling agent evenly to the ultrasound probe. The operator and assistant work together to cover the 3D-printed manipulator arm and the entire ultrasound probe with a sterile sleeve, extrude air bubbles from between the probe and the sleeve, and apply coupling agent evenly to the outer surface of the sterile sleeve where it contacts the patient's skin to complete the preparation of the equipment.

To begin positioning, the operator uses the manipulator arm to gently place the T-shaped ultrasound probe against the patient's neck, positioning the short axis towards the head and the long axis towards the feet. The manipulator arm and rotation axis are adjusted so that the midline of the short-axis image passes through the centre of the internal jugular vein's transverse cross-section. At this point, the laser beam indicates the path to the centre of the internal jugular vein on the body surface, coinciding with the midline of the long-axis probe. After adjusting the rotation axis so that the midpoint of the short-axis probe aligns with the mark, slide the probe 1 cm further towards the head to ensure that the needle tip is closer to the maximum transverse cross-section when puncturing, positioning is then complete.

Once the arm is fixed to ensure the probe remains stable against the skin surface, this creates a hands-free, stable ultrasound guidance system that allows for continuous monitoring throughout the procedure. The operator should stabilise the skin near the puncture site with the left hand, holding the puncture needle at a 45° angle to the skin with the right hand. The needle should be aligned with the laser path and inserted closely alongside the short-axis probe's 'mark' point. Once the needle tip has entered the subcutaneous tissue, we can see the needle tip on both in-plane and out-of-plane real-time ultrasound images, which helps us to determine whether the needle is placed above the highest point of the vein and whether the angle is appropriate. Once the short-axis and long-axis ultrasound images confirm that the needle has entered the vessel and unobstructed, non-pulsatile venous blood is pulled

into the syringe, adjust the needle tip to the centre of the longitudinal section of the internal jugular vein based on the long-axis view. Subsequently, holding the needle in position with the left hand, slide the probe towards the feet with the right hand and, using the short-axis view, determine the needle tip position prior to guidewire insertion using the ‘dynamic needle tip method’; capture a screenshot for scoring the needle tip position during this first-attempt. Maintain the needle tip position, insert the guidewire 30 cm without resistance through the syringe . Guided by the guidewire, advance the internal jugular vein catheter 12–15 cm. If resistance is still encountered, withdraw the guidewire, adjust or withdraw the needle from the internal jugular vein and apply pressure to the puncture site with sterile gauze. After approximately 3 minutes, when there is no significant bleeding at the puncture site, proceed to the next attempt. During this process, the timer is not paused, the number of ultrasound probe repositionings and the number of needle direction adjustments are recorded throughout. If the third-attempt failed or took longer than 10 minutes, a senior physician selected an appropriate technique based on experience or changed the site to complete the central venous catheterization.

The assistant applies coupling agent to the surface of the ultrasound probe. Working together, the operator and assistant cover the probe with a sterile sleeve, extrude air bubbles from between the probe and the sleeve, and apply coupling agent evenly to the outer surface of the sleeve to complete the preparation of the equipment.

To begin positioning, the operator holds the ultrasound probe in their left hand so that its long-axis midline is parallel to the vertical of the internal jugular vein. Once the midpoint of the probe’s long-axis surface aligns with the ‘mark’ point, the probe is slid 1 cm further towards the head along the long-axis midline to ensure that the needle tip is as closer to the maximum transverse cross-section when puncturing. The ultrasound probe is then held steady with the left hand, and positioning is complete.

Hold the puncture needle in the right hand at a 45° angle to the skin, insert the needle closely following the midpoint of the ultrasound probe’s long axis. Once the needle tip has entered the subcutaneous tissue, if the insertion trajectory appears deviated on the long-axis ultrasound image, adjust the insertion angle or reposition the probe to ensure the needle tip enters directly above the internal jugular vein. Once the ultrasound image confirms entry into the vessel and the syringe shows unobstructed venous blood, adjust the needle tip position so that it is situated at the mid-level of the long-axis section of the internal jugular vein. At this point, keep the right hand steady holding the puncture needle, whilst the left hand

holds the ultrasound probe to determine the needle tip position prior to guidewire insertion using the ‘dynamic needle tip method’ via the short-axis view; save a screenshot for scoring the needle tip position during the first attempt. During this attempt, the needle tip is not repositioned; a guidewire is advanced 30 cm without resistance through the syringe. Under the guidance of the guidewire, an internal jugular vein catheter is inserted 12–15 cm and securely fixed. If significant resistance is encountered during guidewire insertion, the guidewire is withdrawn and reinserted after adjusting the intravascular positions of the needle tip. If resistance persists, withdraw the guidewire and the puncture needle from the internal jugular vein and apply pressure to the puncture site with sterile gauze. After approximately 3 minutes, when there is no significant bleeding at the puncture site, proceed to the next attempt. During this process, the operation timer is not paused, the number of ultrasound probe repositionings and the number of needle direction adjustments are recorded throughout. If the third-attempt failed or took longer than 10 minutes, a senior physician selected an appropriate technique based on experience or changed the site to complete the central venous catheterization.

5. Alternative Treatments

Other common options include:

5.1. Opting out of this study and continuing with your standard treatment. Standard treatment methods include the following: conventional ultrasound-guided techniques (adjusting the position of the internal jugular vein within the image whilst adjusting the needle insertion angle), and conventional blind palpation techniques (determining the needle insertion site as 1 cm lateral to the point where the carotid pulse is most prominent on palpation, and adjusting the needle insertion angle according to the anatomical course).

5.2. There are currently no other ongoing studies involving similar techniques at this hospital;

5.3. Declining central venous catheterisation; however, please discuss your decision with your attending physician.

6. Potential Risks and Discomfort

Central venous catheterisation is an invasive procedure; during needle insertion, there is a risk of accidental injury to the nerves surrounding the internal carotid artery or the pleura. However, to ensure patient safety during the procedure, this technique is an essential monitoring method for major surgery.

As the puncture is performed after the patient has been anaesthetised, the patient will not experience any discomfort.

7. Expected Benefits

Compared with traditional techniques, this method offers greater puncture accuracy, a higher success rate, shorter procedure times and a lower incidence of complications, meaning it is more effective and safer.

8. Free Treatment

During the study, participants will not be required to pay any costs associated with the trial. Apart from standard hospitalisation, examination and treatment costs, the investigators will cover all expenses related to the trial.

9. Compensation

Should participants incur necessary expenses as a result of participating in this study, such as travel costs, loss of earnings and nutritional expenses, the investigators will provide reasonable compensation. Compensation will be paid via bank transfer after the study concludes, based on detailed invoices for actual expenses incurred due to participation in the trial.

10. Compensation

As this study aims to improve the quality of healthcare services for young children, should a participant suffer any harm or injury related to the study, the investigators are willing to consult with the participant and provide appropriate support to cover the costs of further treatment for such injuries.

11. Precautions Before, During and After the Study

Please take care to protect the skin on your neck prior to surgery. If you have a history of surgery, trauma or illness involving the neck, please inform the anaesthetist fully when signing the anaesthesia consent form, and also inform the investigator fully at the time of signing this consent form.

12. Confidentiality

Information obtained about you during this trial will be stored in the form of confidential documents in the department’s key patient data repository, where it will be kept strictly confidential and used solely for the

purposes of this study. Public reports of the trial results will not disclose your personal identity. We will make every effort to protect the privacy of your personal medical data within the limits permitted by law.

Only where necessary may the investigator, the research regulatory authority, the Ethics Committee and higher-level auditing bodies be permitted to access your medical records and related information, subject to the signing of a confidentiality agreement. By signing this informed consent form, you agree that your personal and medical information may be used in the circumstances described above.

13. Renewal of Informed Consent

Should changes to the study protocol or updates to safety information necessitate amendments to the informed consent form, the investigator will request that participants sign a new informed consent form. Should this occur, the investigator will exercise their professional judgement; if a new signature is required, participants will be notified in advance.

14. Voluntary Participation

You may choose voluntarily whether to participate in this study, or notify the investigator at any time to withdraw from the trial. Subsequently, your data will be removed from the study results, and your medical treatment and rights will not be affected as a result.

If you require alternative puncture techniques, fail to comply with the study protocol, suffer a study-related injury, or for any other reason, the study physician may terminate your continued participation in this trial.

You may access information and updates regarding this study at any time. Should any new safety information relating to this study arise, we will notify you promptly.

15. Participant Obligations

As a study participant, you have the following responsibilities: to provide truthful information regarding your medical history and current physical condition; to inform the investigator and doctor of any discomfort experienced during the trial; and to inform the investigator and doctor whether you have recently participated in, or are currently participating in, any other studies.

16. Contact Details

If you have any questions regarding this study, or if you experience any discomfort or injury during the study, or if you have any concerns regarding the rights of participants in this study, please contact Li Zhiwen on 18843177788.

If you have any queries or wish to make a complaint about the research staff during the study, please contact the Ethics Committee of the First Hospital of Jilin University on 0431-88782013.

Subject Consent Form

Participant Consent Statement:

□ I have read the above description of this study, and the investigator has explained the details of the study to me in full. I have no further questions regarding the study prior to signing this informed consent form. On this basis, I voluntarily agree to participate in the clinical study described herein, and my decision is based on a full understanding of the potential risks and benefits of participating in this study. Furthermore, the investigators have not used deception, inducement, coercion or any other means to compel me to agree to participate in the study, and I am aware that I may withdraw from the study unconditionally at any stage.

□ As the subject lacks legal capacity or has limited legal capacity, this informed consent form has been signed by the subject themselves.

Signature of participant:

Date:

Participant's contact details:

Investigator's Declaration:

I confirm that I have explained the details of this study to the patient, in particular the potential risks and benefits of participating in this study.

Investigator's Signature:

Date: 30 August 2025

Investigator's Contact Details: 18843177788

Note: This page is the participant's signature page. The investigator must explain the details of the study and all relevant information to the participant in detail. The informed consent form must be signed by both the participant and the investigator who provided the explanation. If the participant has any questions regarding the study, the investigator must immediately provide a detailed explanation in person. Once signed, both the investigator and the participant shall retain one original copy each.