Informed consent for clinical studies on safety and precision of radial artery catheterization

Dear patients:

You will be invited to attend a clinical study. This informed consent form provides you some information to help you decide whether to participate

Add to this clinical study. Please read it carefully and ask any questions to the investigator responsible for the study.

This study will be conducted jointly in the Department of Anesthesiology of Nanjing First Hospital and Nanjing Jiangning Hospital of Traditional Chinese Medicine, and an estimated 100 study participants will participate voluntarily. This study has been reviewed and approved by the Ethics Committee of Nanjing First Hospital and the Ethics Committee of Nanjing Jiangning Hospital of Traditional Chinese Medicine, and 10 cases are expected to be enrolled in Nanjing First Hospital.

If you wish, please read the following carefully.

Protocol name: Clinical study on the safety and precision of ultrasound-guided radial artery puncture and catheterization

Protocol version number and date: v 1.0 2023-07-22

Informed Consent Form Version number and Date: v 1.0 2023-07-22

Research Center: Department of Anesthesiology, Nanjing First Hospital

Principal investigator: The Korean Wave

I. Research purpose

With the continuous development and clinical popularization of invasive blood pressure monitoring technology (ABP), the safety of patient anesthesia has been greatly guaranteed. The radial artery is superficial, and the forearm has a dual blood supply to the radial and ulnar arteries, so it is the first choice for arterial puncture and catheterization.

It has been reported in the literature that the distal quarter of the forearm is the best insertion site for ultrasound-guided radial artery puncture, and the selection of the middle radial artery forearm catheterization improves the success rate and overall success rate of the first puncture attempt, and reduces the incidence of hematoma during puncture.

Invasive radial artery puncture cannot completely avoid complications, such as puncture hematoma, arterial occlusion, infection, pseudoaneurysm, vasospasm, and neurovascular injury have been reported in the literature.

There are no recommendations for the best puncture site for radial artery puncture. Therefore, it is particularly important to choose a more appropriate and safe and accurate location as an ultrasound-guided radial artery puncture catheter.

2. Study process and precautions

This study is intended to further compare the influence of radial artery position by observing the position distance of radial artery (ulnar: radial), radial artery (center) distance, vertical distance from skin, and radial artery (ulnar: radial). At the same time, it is planned to observe the success rate of first puncture, puncture insertion time, puncture number and puncture related complications at different distances of the forearm during radial artery puncture insertion. An estimated 100 study participants will volunteer. The study period was from 22 July 2023 to 30 June 2024. If you agree to participate in this study, we will number each subject to establish the medical records. You make

Participation in the study is fully voluntary, and you can be informed of the information and progress of the study, and decide to participate (continue) or not (continue).

3. Who who can / can not participate

1. Inclusion criteria: (1) elective surgery patients scheduled to undergo general anesthesia and invasive arterial blood pressure monitoring; (2) ASA grade I~; (3) age 18 to 65 years; (4) agree to participate in this clinical study and sign informed consent.

2. Exclusion criteria: (1) positive or suspicious positive Allen patients; (2) peripheral vascular diseases; (3) coronary artery related diseases; (4) local skin infection, rupture, scar and surgical history; (5) shock patients or receiving strong heart drugs, vasoconstriction drugs; (6) peripheral nerve injury, anatomical abnormalities and neurological function; (7) passive upper limb body position, unable to complete ultrasound assessment.

Iv. Risk and discomfort

For you, all the information will be kept confidential. Invasive radial artery puncture cannot completely avoid complications at certain times, such as puncture hematoma, arterial occlusion, infection, pseudoaneurysm, vasospasm, neurovascular injury, etc. The protective measures for the study participants are: in the event of serious radial puncture complications during the experiment, the experiment was immediately stopped immediately, and the complications were treated actively and effectively.

Four, benefit

Studying your data will help improve the safety and precision of radial artery catheterization. Study results will not be fed back to study participants.

V. Funds issues

The cost of ultrasound examination in this project is free, and there is no experimental operation other than treatment, so no research funds related to the study. Also, you will not receive any form of remuneration.

Five, responsibility

As a subject, you have the following responsibilities: provide your medical history and current physical condition; tell the study doctor of any

discomfort during the study, not taking restricted medication, food, etc.; tell the study doctor if you have participated in or are currently participating in other studies.

6. Privacy issues

If you decide to participate in this study, your participation in the trial and your personal data during the trial are kept confidential. Information that can identify you will not be disclosed to members outside of the study team without your permission. All study members and study sponsors are required to keep your identity confidential. Your file will be kept in a locked file cabinet for researcher access only. To ensure that the study is conducted in accordance with the regulations, members of the government administration or the ethics review committee can access your personal data at the study site if necessary. No personal information of you will be disclosed on publication of the results of this study.

Besides this study, it is possible that your experimental data will be used again in other future studies. You may also now declare rejecting other studies than this study to utilize your medical records and experimental data.

Vii. Rights

If you are injured by participating in this study: you can receive free treatment and / or corresponding compensation for any damage related to the clinical study.

You may choose not to participate in this study or at any time notify the investigator to withdraw from the study, your data will not be included in the study results and any medical benefits and interests will not be affected.

If you need other treatment, or if you do not comply with the study plan, or have a study-related injury or for any other reason, the study physician may terminate your continued participation in the study.

You can keep abreast of the information and progress of the study. If you have any questions related to the study, contact the researcher at 02587155030, or any discomfort or injury occurred to you during the study, or about the interests of participants in the study, you can contact the hospital Ethics Committee at any time at 02552271064.

informed consent

I have read this informed consent form.

I have the opportunity to ask questions and all the questions have been answered.

I understand that participation in this study is voluntary.

I may choose not to participate in this study or withdraw at any time after notifying the investigator without discrimination or reporting Well, any of my medical treatment and interests will not be affected.

If I need other treatment, or I do not comply with the study plan, or have a study-related injury or for any other reason, the study physician may terminate my continued participation in this study.

I will receive a copy of the informed consent form that I have jointly signed with the investigator.

Finally, I decided to consent to participate in this study.

Study Participant Signature:_____Signature Date:_____
Year _____ month _____ day

Contact number:_____

If the study participant is unable to sign the informed consent due to incapacity or other reasons, it shall be signed by his legal representative or guardian.

Signature of legal representative or guardian: _____ Relationship with study participants: _____ Study participants can not sign informed consent Reasons: _____ Contact: _____ Date: ____, _____, _____

I have accurately informed the subject of the document, and he / she had accurately read the informed consent form and demonstrated that the subject had the opportunity to ask questions. I testified that he / she had voluntarily agreed to it.

Investigator's signature:_____Signature Date:_____
Year _____ month _____ day

Investigator Contact Number:_____