The research plan

Clinical study protocol for safety and precision of radial artery catheterization

Research unit: Nanjing First Hospital

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Years of study: July 2023-June 2024

Version number: V1.0

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scenario summary

research design **(Can be selected more)**	☐ case-control study ☐ cohort study ☐ cross-sectional study ☐ other: ☑ Randomized controlled study ☐ applied the blind method
Study type **(Please follow the project Type check)**	●Concomitant diagnostic kit study ☐ Retrospective study of previous clinical data ☐ Retrospective study of previous clinical specimens ☐ Establish a specimen library study ☐ Establish a cohort study ☐ Previous individual cases were reported ☐ Study of non-implantable medical devices (face mask, dental pad, etc.) ☐ Five years of marketed drug study (including chemical drugs, generic drugs, etc.) ☐ Listed device study (including AI, imaging software) ☑ Others (for the investigator's judgment, please specify:)
Total number of cases	100 Cases
Risk / benefit analysis	Risk: The study may have a radial artery puncture injury; Benefits: Select a more appropriate and safe and accurate location for clinical practice as an ultrasound-guided radial artery puncture placement Pipe parts.

risk judgement	☑ Not greater than the minimum risk ☐ is greater than the minimum risk Minimum risk: the likelihood and extent of expected risk in the trial is not greater than routine or routine

	Risk of grid examination or psychological testing
The study period	From 22 July 2023 to 30 June 2024

1. research background

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, thus becoming an arterial puncture

The first choice for catheterization.

It has been reported that the distal quarter of the forearm is the best insertion site for ultrasound-guided radial artery puncture, and the selection of the radial forearm catheterization improves the success rate and the overall success rate of the first puncture attempt

Prevalence of hematoma during the puncture process.

Invasive radial artery puncture sometimes cannot completely avoid complications, such as puncture hematoma and artery closure

Complications such as plug, 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, the choice is more appropriate and safe

Fully accurate location as ultrasound-guided radial artery puncture and catheterization is particularly important.

2. purpose of research

1. Main objective: To evaluate the anatomical parameters of the radial artery based on ultrasound imaging in the forearm,

Provide a reference to ultrasound anatomy for the clinical implementation of radial artery puncture.

2. Secondary objective: To find the best site of radial artery puncture to improve the safety and accuracy of radial artery puncture and catheterization.

3. Study design, methods, and study procedures

1. Study design

In this study, we plan to further compare the position distance between the radial artery and the radial artery, the vertical distance from the radial artery (center), and the distance between the radial artery (ulnar: radial)

The influence of age, BMI and left and right side on the radial artery position.

At the same time, the radial movement is intended to be guided by ultrasound at different distances during the radial artery puncture

Success rate of first puncture, puncture catheterization time, number of puncture and puncture related complications.

The sample size of this study was calculated according to the results of the pretest. The main observation indicators were the vertical distance between the radial artery and the radial artery (radial artery), set statistical efficiency 1- β =0.9, test standard α =0.05, n =30, calculated n = 30, the case loss rate was set at 15%, and the final sample size was 100

example.

2. Research methods

The anatomical relationship and influencing factors of the radial artery were observed by ultrasound, and then the optimal puncture position was selected and the puncture was guided

Reduce the number of punctures, reduce the complications, and improve the safety and precision.

3. Study steps

Main study steps: patients in the supine position, both upper limb abduction, palm up, wrist angle of 45 °, using a portable ultrasound instrument (probe frequency 13-6 MHz, Sonosa), the ultrasound probe in the direction of the short axis in the radial artery (from the radial artery) to the radius for the projection of the radial artery), the relative distance of each anatomical site was 2cm. There was no significant compression of the radial artery to maintain the normal shape and site of the vessel. The radial diameter of the radial artery, the vertical distance from the skin, and the radial god were measured

Distance relative to the radial artery (ulnar: radial). And recorded according to gender, age, BMI, and left and right sides.

Secondary study objective steps: the radial artery surface projection was divided into three sections. The first segment is in the

range of 0-5cm from the proximal to the radial stem, the second segment is in the range of 5-10cm from the proximal to the radial stem, and the third segment is in the range of 10cm to the proximal cubital fossa. And the puncture site was divided into the first stage of the left hand, the second section of the left hand, the third section of the left hand, the first section of the right hand, the second stage of the right hand, and the third section of the right hand; the experimenter randomly selected the puncture site, and used the portable ultrasound instrument (probe frequency 13-6 MHz, Sonos), and the in-plane puncture technique was used to puncture the radial artery, and the first puncture success rate, puncture insertion time and puncture times were recorded
And puncture-related complications.

4. Case selection

1. Inclusion criteria: (1) patients undergoing elective surgery 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 the informed consent form.

2. Exclusion criteria: (1) Allen positive or suspicious positive patients; (2) peripheral vascular diseases; (3) coronary artery related diseases; (4) local skin infection, rupture, scar and surgical history; (5) shock patients or acceptance, heart drugs, vasoreduction drugs; (6) peripheral nerve injury, anatomical abnormalities and neurological abnormalities; (7) upper limbs

The atic, not unable to complete the ultrasound assessment.

3. Termination criteria: Patients may withdraw their consent and withdraw from the trial at any time.

Any medical condition in the study that poses a risk that the continuing study subject may be terminated by the study physician Continued to participate in this study;

And the study physician may terminate if the patient fails to comply with the study plan, or if a study-related injury occurs

Continue to participate in this study;

The investigator judged the other conditions that should be withdrawn from the trial.

5. Other alternative methods of diagnosis and treatment are available

If the radial artery puncture is unsuccessful, non-invasive blood pressure monitoring of the upper arm cuff is feasible.

Vi. Test items and test time points

After entering the patient into the room, the position distance between the radial artery (the radial artery, radial artery, radial artery, radial artery (center) vertical distance from the skin, and the distance of the radial nerve (ulnar: radial side) were measured. At the same time, the first puncture of radial artery puncture at different distances of the forearm was recorded

Power, puncture and catheterization time, number of puncture times, and puncture-related complications.

7. Efficacy evaluation criteria

Complete and accurately record all data, operation time, frequency and success rate.

Viii. Observation, recording and disposal of adverse events

You will be followed up and evaluated within 3 days of the study. In case of serious radial artery puncture complications during the experiment, the experiment will be stopped immediately, and the adverse events will be recorded and reported to the project leader. Positive and effective

Follow-up records according to the type of complications.

IX. Research quality control and quality assurance

not have

X. Data security monitoring

The clinical study will develop a corresponding data safety monitoring plan according to the risk size. All bad events should be recorded in detail, properly handled and tracked until properly resolved or in stable condition, and timely submitted to the ethics committee and the competent department in accordance with the regulations

Door, sponsor and drug to report serious adverse events and unexpected events; principal investigator regularly

A cumulative review of all adverse events and an investigator meeting if necessary to assess the risks and benefits of the study; both

Emergency unblinding may be performed when necessary to ensure subject safety and equity.

Xi. Statistical treatment

Using SPPS 22.0 software, the measurement data with mean ± standard deviation ($\bar{x}\pm$ s), ANOVance between groups; count data are presented as example or percentage, with 2 test, P 0.05χ

The difference was statistically significant.

Xii. Ethics principles and requirements for clinical research

Clinical studies will follow the Declaration of Helsinki of the World Medical Congress and the Measures of the National Health and Family Planning Commission of the People's Republic of China, and implement informed consent,

Protect privacy, research free and compensation, risk control, special subject protection and compensation principles and requirements for research related damages. The clinical study was performed before EC approval of the study protocol. Before each subject is enrolled in the study, the Investigator has the responsibility to fully and comprehensively present the purpose, procedures and possible risks of the study, and their legal representative and to sign a written informed consent form that their participation in the clinical study is entirely voluntary, that they may refuse to participate or withdraw from the study at any stage of the trial without discrimination and retaliation, and their medical treatment and interests are not affected. The informed consent form should be kept as a clinical study document for future reference to effectively protect the personal privacy and data confidentiality.

Xiii. Research progress

July 2023-August 2023: Trial implementation

August 2023-March 2024: Collect and collate data

March 2024- -June 2024: Writing the paper