Informed consent Version 1.0 2020.01.07

Title:Observational multicentre pilot study of the incidence of complications at different tip positions of the midline catheters

Dear lady / sir:

We are about to conduct an observational multicenter study of the incidence of complications at different locations on the tip of a medium-length catheter. You may be eligible for this study. Therefore, we invite you to participate in this study. The sponsor of this study is Department of Intravenous Treatment, Shao Yifu Hospital Affiliated to Zhejiang University School of Medicine, the main researcher is XXX, the chief nurse of the department of intravenous treatment. This informed consent will introduce you to the purpose and steps of the study, the benefits it brings to you, the risks you will bear, the inconvenience or discomfort and the main items of the study, and also introduce you to other treatments you can choose And you have the right to withdraw from the study at any time. Please read carefully and make a decision carefully whether to participate in the study. When the researcher explains and discusses the informed consent form, you can ask questions at any time and let him / her explain to you what you do not understand. You can discuss with family members, friends, and your doctors and nurses before making a decision. Your signature will not cause you to lose any legitimate rights and interests, and the original signed informed consent will remain with the researcher.

1. Introduction of the study

The medium-length catheter is a peripheral venous access of 8-25 cm. The American Infusion Nurses Society (INS) practice

standard for infusion therapy indicates that the nature of the infusion drug is the same as that of a peripheral venous indwelling needle, and the expected duration of use is 1-4 weeks. At present, the average hospital stay of Chinese patients is 10 to 15 days, and more than 80% of inpatients require intravenous infusion. Medium-length catheters can meet the needs of this part of inpatients. However, literature shows that medium-length catheters compare The incidence of phlebitis is lower than that of peripheral venous indwelling needles; the incidence of deep vein thrombosis and catheter-related bloodstream infections is lower than that of central venous catheters. In addition, there is no need to take a chest radiograph and other methods to position the head end after placing a medium-length catheter, which reduces radiation exposure and costs. It can be used immediately after the catheter is placed and reduces the waiting time for treatment. However, there are some complications in medium-length catheters, such as upper limb catheter-related thrombosis, phlebitis, and tube obstruction. In addition to the patient's own situation and operation, the occurrence of these complications is related to the length of medium-length catheter insertion and There is a clear relationship between the tip position, but there are no clear regulations on the length of the medium-length catheter insertion and the position of the catheter tip at present. The literature reports that the insertion length varies from 8-25CM, and the catheter tip position is mainly at The axillary vein, the opening of the axillary vein of the cephalic vein, and the subclavian vein are also located, and the guidelines are not uniform. These uncertain factors make the clinical application of the catheter quite different, leading to an increase in the incidence of some complications and new problems, which trouble medical personnel

and urgently need to be resolved.

The purpose of this study is to carry out a multi-center clinical study. The main research literature and guidelines mention that the catheter tip is located in the axillary vein and the subclavian vein. Explore the optimal head position of medium-length catheters, and provide reliable evidence for the safe and reasonable application of medium-length catheters in clinic.

2.Your responsibilities

a) Provide accurate past medical history and current condition information.

b) Tell the investigator and the doctors and nurses about any health problems you have during the study.

c) Do not participate in other clinical studies.

d) Follow the guidance of researchers, doctors and nurses.

e) If you have any questions, you can always ask.

3.Risks and discomfort

Your researchers, doctors, and nurses will monitor for complications or adverse reactions. If during the study, you have any adverse reactions or discomforts, such as: being unable to tolerate uncomfortable conditions such as catheter indwelling and some complications related to venous access indwelling such as phlebitis, catheter-related thrombosis, catheter-related infections, and catheter puncture site bleeding

Infiltration, catheter slippage, catheter blockage, etc., are immediately reported to the researchers, doctors, and nurses. This is very important. If you or your researchers, doctors, or nurses think you cannot tolerate, the catheter may be completely Disabled, you may withdraw from this study. We will assess the function of the catheter and whether there are complications.

4. Benefit

Based on the results of previous studies, the difference in efficacy between the three is unclear. The information obtained from your participation in this study may be of guiding significance for future patients receiving relevant vascular access programs. Based on the results of previous studies, it is expected that whether you are assigned to experimental group 1 (cephalic end in the subclavian vein), experimental group 2 (cephalic end in the axillary vein) or control group (cephalic end not reaching the axillary vein group), the therapeutic effect is not low Because of the standard medium-length tube placement technique, and the information you obtained from participating in this study may be instructive for patients to receive related tube placement in the future.

5.Cost

In contrast to conventional medium-length catheter placement, in addition to the cost of materials required for conventional catheter

placement, the cost of ultrasound-guided treatment and the location of X-ray chest radiograph after placement, the cost of conventional catheter maintenance and other treatments, this study No additional treatment costs are incurred. In addition, the ultrasound examination of the catheterization endometrium before catheterization and the ultrasound examination of the catheterization endometrium after extubation are free items.

6.Confidentiality

Any information and data about you obtained during the research process will be kept strictly confidential. Information that can identify you will not be disclosed to members outside the research team unless you have your permission. All research members and sponsors are required to keep your identity confidential. Your file will be kept in a locked data cabinet, which is only for the researchers to consult. In order to ensure that the research is carried out in accordance with the regulations, if necessary, the government management department, the sponsor authorized by the sponsor or the ethics committee members can access the relevant information about your participation in the research unit according to the regulations, but they will ensure that your information is not disclosed to other parties information. Although the research results may be published, your identity will not be disclosed in these publications. The research materials will be kept in Shao Yifu

Hospital Affiliated to Zhejiang University School of Medicine.

7.Your rights and handling of adverse events

Whether to participate in the study depends entirely on your voluntary. You can also refuse to participate in this research, or withdraw from this research at any time during the research process, your medical treatment or legal interests will not be affected in any way. If you do not participate in this study, or withdraw from the study halfway, there are many other alternative treatment and nursing techniques, you do not have to choose to participate in this study in order to treat your disease. If you need to withdraw from the study, for your safety and objective evaluation techniques, please cooperate with the researchers, doctors, and nurses to complete the relevant evaluations and examinations after the study. Your researchers, doctors, and nurses will monitor the adverse effects of the study throughout. If you have any adverse reactions or discomfort during the study, such as: being unable to tolerate uncomfortable conditions such as catheter indwelling, etc., immediately report it to the investigator, doctor, or nurse.

Informed Consent Sign page

I have read this informed consent.

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

I understand that participation in this study is voluntary.

I can choose not to participate in this study, or I can withdraw from the researcher at any time without being discriminated against or retaliated against, and any of my medical treatment and rights will not be affected as a result.

If I need other treatments, or if I do not follow the research plan, or if there are injuries related to the research, or for any other reason, the research physician can terminate my continued participation in this research.

I will receive a signed copy of the "informed consent".

Subject signature: _____

Date: _____ year ____ month _____ day

If the subject cannot sign the informed consent due to incapacity or other reasons, or if the subject is a minor, the guardian shall sign.

Guardian's signature: _____

Relationship with subjects: _____

Date: _____ year ____ month _____ day

I have accurately informed the subject of this document, and he / she

has read this informed consent accurately and proved that the subject has the opportunity to ask questions. I prove that he / she voluntarily agreed.

Researcher's Signature: _____

Date: _____ year _____ month _____ day Tel: 0571-86006829

For ethical matters, please consult: Medical Ethics Committee of Sir Run Run Shaw Hospital, Zhejiang University School of Medicine, 0571-86006811