"Clinical Study of the Accuracy of Blood Pressure Measurement by Fishy YE990 Medical Fully Automatic Electronic Sphygmomanometer" Information for Subjects

Protocol name: Clinical study on the accuracy of blood pressure measurement by YE990 medical automatic electronic sphygmomanometer of Yuyue

Protocol version number version date: V1.0, April 15, 2024

Informed Consent Version No. Version Date: V1.0, April 15, 2024

Institution: The First Affiliated Hospital of Anhui Medical University

Principal Investigator (Physician in charge of the study): Liu Hejun

You are being invited to participate in a clinical research study. This information sheet gives you information to help you decide whether or not to participate in this clinical study. Please read it carefully and ask the investigator in charge of the study if you have any questions.

Your participation in this study is voluntary. This study has been reviewed by our Institutional Ethics Review Board.

Purpose of the study: Blood pressure is the lateral pressure on the vessel wall when the blood flows in the blood vessel, and it is a comprehensive reflection of hemodynamic changes such as circulating blood volume, cardiac output, peripheral vascular resistance and arterial wall elasticity, etc. It is used as an important indicator to assess the status of the patient in the clinic, and the correctness or otherwise of the measurement value directly affects the diagnosis, treatment, care, and prognosis of the related diseases. Clinical sphygmomanometers are mainly mercury column sphygmomanometers and electronic sphygmomanometers, among which mercury column sphygmomanometers are widely used in clinical practice due to their stable physical properties, accurate measurement, easy use, convenient maintenance and other advantages, and have long been regarded as the "gold standard" in blood pressure measurement. However, traditional mercury sphygmomanometers contain mercury that pollutes the environment, and if used improperly or during transportation, the mercury in the sphygmomanometers is easily lost, which has a negative impact on the human body and the environment, and also leads to inaccurate blood pressure measurement.In its place, electronic sphygmomanometers have been gradually adopted in clinics and homes on the basis of

their non-polluting and easy-to-use advantages. Accurate electronic sphygmomanometers can improve people's compliance with blood pressure measurement, allow blood pressure monitoring at any time, and to a certain extent facilitate the acquisition of more accurate data, thus providing a series of valuable information for patient assessment, treatment results and evaluation of the efficacy of new drugs. However, the first issue that needs to be addressed in order for electronic sphygmomanometers to fully replace mercury column sphygmomanometers is the accuracy of their measurements, i.e., the consistency of the measurements between electronic sphygmomanometers and mercury column sphygmomanometers. The purpose of this study was to confirm the accuracy of the YE990 electronic sphygmomanometer by comparing the measurements of the electronic sphygmomanometer and the mercury column sphygmomanometer.

Study procedure: This study was conducted in only 1 medical institution, the First Affiliated Hospital of Anhui Medical University, and a total of no less than 85 subjects were planned to be enrolled in this study as follows.

(1) Before you are enrolled in the study, the research doctor will give you a detailed introduction of the study, the requirements, benefits and risks of participating in the trial, etc. If you voluntarily participate in the study, you will be required to sign this Informed Consent Form; if you do not wish to participate in the study, the doctor will deal with you according to clinical diagnosis and treatment routines.

After signing the Informed Consent Form, the doctor will ask and record your basic information, medical history, combined medications or treatments, and carry out vital signs and other checks.

(2) After these checks, if you are suitable for this study, you will be selected to enter the study.

The study will be conducted in a quiet and comfortable environment. A trained researcher will measure your blood pressure and pulse rate several times with a mercury column sphygmomanometer and a Yuyue YE990 automatic electronic sphygmomanometer according to the requirements of the study protocol, and record the measured data.

The number of measurements is usually no more than 8, with more than 1 minute between each measurement.

The study is completed 30 minutes after the measurements have been taken if you are not feeling unwell.

You should tell the researcher your past medical history, medication history, etc., and cooperate with the researcher in the measurement of your blood pressure. If you have any discomfort or factual situation during the study, please inform the researcher truthfully. We will communicate with you or your family members to introduce the study to you. If you agree to participate in the study, please provide information about your disease, including the onset of the disease, family history, previous visits to the doctor, and the results of some tests you have taken. Each participant will be numbered and a medical record will be created.

Risks and Discomfort: It may be a little psychologically uncomfortable for you to communicate and talk with us. This study focuses on the measurement of blood pressure, which is non-invasive. Possible adverse reactions are allergies to the cuff or discomfort caused during the measurement of pressurization.

Benefit: The study of your informational data will provide necessary recommendations for your treatment or provide useful information for disease research. Participation in this study may also provide data to support the use of the fully automated electronic sphygmomanometers studied in this research, which will provide a reference for their clinical use and may bring convenience to more patients.

COST: Participation in this program is free of charge and all costs incurred will be borne by the sponsor.

Compensation: To compensate for the inconvenience that participation in this study may cause you, you will receive $200 in transportation reimbursement upon completion of the study.

PRIVACY ISSUES: If you decide to participate in this study, your personal information about your participation in the study and during the study is confidential. The physician in charge of the study and other researchers will use your medical information to conduct the study. This information may include your name, address, telephone number, medical

history, and information obtained during your research visit. Your file will be kept in a locked file cabinet and will be accessible only to researchers. To ensure that the research is conducted in accordance with the regulations, members of the government administration or the ethical review board are required to have access to your personal data at the research unit when necessary. The results of this study will be published without disclosing any of your personal data.

If you are harmed as a result of your participation in this study, you may be entitled to free medical treatment and/or appropriate compensation in the event of clinical research-related damage.

You may choose not to participate in this study, or you may request to withdraw from the study at any time by notifying the investigator that your data will not be included in the results of the study, and any of your medical treatment and rights will not be affected as a result.

The research physician may terminate your continued participation in this study if you need other treatment, if you do not follow the study plan, if a study-related injury occurs or for any other reason.

You will be kept informed of information and research progress related to this study, and you will be notified of any new safety information related to this study. If you have questions about this study, or if you experience any discomfort or injury during the study, or if you have questions about your rights as a participant in this study, you may contact John Liu at 13856001718 (cell phone number).

If you have any questions or claims about the rights and health of the participants in this study, you can contact the Ethics Committee of this organization at 62923102; contact person: Chen Yihao.

Informed Consent Signature Page

I have read this informed consent form.

I have had the opportunity to ask questions and all 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 by notifying the researcher without discrimination or retaliation, and none of my medical treatment or rights will be affected as a result.

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

I will receive a signed copy of the Informed Consent Form.

Subject's name: _____

Subject's Signature: _____

Date: _____ _Year _____ _Month _____

I have accurately communicated this document to the subject, requesting that he/she read this informed consent form carefully and answer any questions or concerns raised.

Name of researcher: _____

Investigator's signature: _____

Date: _____ _Year _____ Month _____ Day

(Note: Witness signature is required if the subject is illiterate, or proxy signature is required if the subject is incapacitated)