Study protocol

Abstract

Hypertension is the most important risk factor that is closely related to the occurrence, development and deterioration of cardiovascular and cerebrovascular diseases. Therefore, the early diagnosis of hypertension is particularly important. At present, the monitoring of blood pressure can be divided into two modes: invasive and non-invasive blood pressure monitoring. Invasive arterial blood pressure monitoring is currently the "golden standard" for assessing arterial blood pressure, but because of its invasiveness, the complex operation, and the risk of infection and thrombosis, it is only clinically applicable to the monitoring of critically ill patients. At present, the blood pressure diagnosis mode commonly used in clinical practice is a non-invasive hypertension monitoring mode, which is a static and passive diagnosis method. The principles of the monitoring are mostly the Korotkoff sound method and the oscillography method. But those methods have some shortcomings, such as discontinuity and contingency. Photoplethysmography is the most advanced monitoring principle of wearable sphygmomanometer in the world. The test equipment is a pulse wave blood pressure diagnostic device (VITA-D1) based on artificial intelligence. It is non-invasive, easy to operate, and can continuously monitor blood pressure. The device has received the certification of the China Food and Drug Administration (CFDA). This study aims to validate the accuracy and consistency of photoplethysmographic sphygmomanometers (VITA-D1) in order to provide a more comfortable and convenient blood pressure monitoring device.

Study purpose

To observe the accuracy of a novel sphygmomanometer (VITA-D1 sphygmomanometer, VITA-Course Technologies CO., LTD.) based on photoplethysmography, in order to provide a more comfortable and convenient blood pressure monitoring device

Primary outcome measure

Mean values, standard deviation and 95% confidence interval of systolic blood pressure, mean blood pressure and diastolic blood pressure between the devices.

Secondary outcome measures

1. Pulse rate oxygen saturation of blood
2. Incidence of health issues and equipment failure following the blood pressure measurement:

2.1. Allergy

2.2. Itch

2.3. Equipment out of action or other failures

2.4 Others.

Clinical trial design

This is a diagnostic test of an innovative blood pressure monitoring device.

Three hundred participants in multiple centers will be enrolled in this study and divided into 3 parts. There are 100 participants in each part. We record the medical history, routine

physical examination and a serious of necessary laboratory tests of each participant. All the participants receive blood pressure measurement with photoplethysmographic sphygmomanometers and participants in each group measure their blood pressure with invasive blood pressure monitoring (Part 1), mercury sphygmomanometer (Part 2) and 24-hour ambulatory blood pressure measurement (Part 3), respectively.

Part 1: Invasive blood pressure monitoring:

A professional doctor takes the right radial artery as the puncture point and inserts the puncture catheter directly into the artery. The invasive blood pressure values are obtained by connecting the pressure measuring tube with the transducer. At the same time, another researcher uses photoplethysmographic sphygmomanometers (VITA-D1) to measure blood pressure in the right index finger. Each participant will be recorded for 2 minutes.

Part 2: Before measurement:

Within 30 minutes before blood pressure measurement, participants are not allowed to smoke, drink tea or coffee, and should empty the bladder. They should be seated comfortably and relaxed for at least 5 minutes, her/his back and arm supported with the middle of the upper arm at heart level, legs uncrossed, and feet flat on the floor. Talking and any other interference needs to be avoided throughout the entire validation procedure.

Blood pressure measurement with photoplethysmographic sphygmomanometers and mercury sphygmomanometers: Two researchers use mercury sphygmomanometers with a “Y-type” stethoscope connecting two receivers with a Y-connector and one researcher use photoplethysmographic sphygmomanometers (VITA-D1) to measure the right arm and right index finger blood pressure of the same subject three times, respectively. Each interval is 1-2 minutes. The appropriate length and width of mercury sphygmomanometer cuff is selected according to the arm circumference of the subjects. Blood pressure measurements with mercury sphygmomanometer are expressed by the mean of the measurements of two researchers. If the difference of blood pressure measurement between two researchers is less than 4 mmHg, the mean of two measurement values is taken as the measurements of the observers. If they are larger than 4 mmHg, they need to be re-measured. The measurement value of VITA-D1 is expressed by the mean of the measurement values of a researcher. The results are recorded and analyzed.

Part 3: 24-hour ambulatory blood pressure measurement:

24-hour ambulatory blood pressure measurement is performed on the right upper arm and right index finger with AND Ambulatory Sphygmomanometer and photoplethysmographic sphygmomanometers (VITA-D1) separately. Blood pressure is measured every 30 minutes from 6am to 10pm and every 1 hour from 10pm to 6am.

Study population

Inclusion criteria:

1. Age from 25 to 80 years old
2. Volunteer to participate in this study and sign the informed consent
3. Requiring arterial blood pressure monitoring
4. Distribution of the blood pressure is in accordance with American National Standards Institute (ANSI)/AAMI/ISO standard revision 2013 (ISO 81060–2:2013).

exclusion criteria

1. Any persistent arrhythmias and/or atrial fibrillation
2. Upper limb fracture, trauma, infection, arteriovenous fistula, etc. that might impact the blood pressure measurement
3. Pacemaker installed
4. Fingers with nail polish or nail painting
5. Uncooperative participants with a disordered PPG curve
6. The other cases that the investigators determine to be unsuitable for participation in the study