ISRCTN13366089 https://doi.org/10.1186/ISRCTN13366089

Clinical application of continuous cuffless blood pressure monitoring based on optically measured changes in light absorption by blood vessels

Submission date 03/11/2019	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 06/01/2020	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 10/01/2020	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
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

Who can participate?
Patients aged from 25 to 80 and volunteer to participate in this study and sign the informed consent

What does the study involve?
Three hundred participants are allocated to three parts. The patients undergo blood pressure

measurement to evaluate the consistency between photoplethysmography pulse wave sphygmomanometer and invasive blood pressure monitoring, mercury sphygmomanometer, 24-hour ambulatory blood pressure measurement respectively

What are the possible benefits and risks of participating?
The main benefit will be to provide an understanding of blood pressure values and prevention, diagnosis and treatment of hypertension for participants. There is no risk of participating in this study

Where is the study run from?
The first affiliated hospital, Sun Yat-Sen University (Guangzhou, China)

When is the study starting and how long is it expected to run for?
November 2019 to May 2020

Who is funding the study?
Investigator and VITA-COURSE Technology CO., LTD funded

Who is the main contact?
Jun Tao
Taojungz123@163.com

Contact information

Type(s)
Scientific

Contact name
Prof Jun Tao

ORCID ID
https://orcid.org/0000-0002-2226-765X

Contact details
Department of Hypertension and Vascular Disease
The First Affiliated Hospital of Sun Yat-sen University
No. 58 Zhongshan Second Road
Guangzhou
China
510080
+86 13922191609
zsyyyb@mail.sysu.edu.cn

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
[2019]345

Study information

Scientific Title
Consistency evaluation of non-invasive continuous cuffless blood pressure monitoring based on photoplethysmography compared with invasive blood pressure monitoring, mercury sphygmomanometer and 24-hour ambulatory blood pressure measurement

Study objectives
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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/09/2019, the Ethics Committee of the First Affiliated Hospital, Sun Yat-Sen University (No. 58 Zhongshan Second Road, Guangzhou, China; +86-020-87755766; linhf7@mail.sysu.edu.cn), ref: [2019]345

Study design
Diagnositc study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Hypertension

Interventions
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.

Intervention Type
Device

Phase
Not Applicable

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

Key secondary outcome(s))
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

Completion date

01/09/2020

Eligibility

Key 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).

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key 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

Date of first enrolment
01/11/2019

Date of final enrolment
01/07/2020

Locations

Countries of recruitment
China

Study participating centre
The First Affiliated Hospital, Sun Yat-Sen University
Guangzhou
China
510080

Sponsor information

Organisation
Department of Hypertension & Vascular Disease, The First Affiliated Hospital, Sun Yat-Sen University

ROR
https://ror.org/037p24858

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Funder Name
VITA-COURSE Technology CO. LTD.

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		25/12/2019	10/01/2020	No	No