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Evaluation of cardiovascular state using camera images compared to traditional contact methods

Submission date
15/05/2017

Recruitment status
No longer recruiting

Registration date
30/05/2017

Overall study status
Completed

Last Edited
22/04/2021

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Image-based vital signs monitoring has developed rapidly in the last decade and now there are multiple smart phone applications can detect heart rate and breathing rate using the camera. These developments open up the possibility to be able to monitor patients fully using their skin as a window rather than use multiple machines that can cause pain or discomfort. Doctors use signs that reflect perfusion of distal parts of the body (further away from the centre of the body) such as hand/feet skin temperature to make an assessment of how well the patient's heart is working. When the heart is not pumping enough blood to meet the requirements of the body, it is expected that hands and feet to be cooler to touch as the body automatically redirects blood to the more vital and central areas. Based on this, it is predicted that it is possible to monitor changes in heart function using a camera. More specifically, it is expected that different skin response of core areas (face/chest) and distal areas (hands/feet) to increased /reduced heart function may be used to estimate the overall cardiovascular function. This research could be helpful in a critical care setting where a close monitoring of patients' heart function is necessary therefore requiring multiple invasive monitors are placed on patients despite their potential complications/infection risks. A camera would provide a pain-free and risk-free alternative. The aim of this study is evaluate if camera imaged can detect the response of central and distal areas of the skin to cardiovascular changes.

Who can participate?
Healthy volunteers aged 18 to 60 years old

What does the study involve?
Participants undergo two tests while being monitored with four different types of monitoring devices. The first established method of monitoring uses a machine called a bioimpedance monitor. This machine passes small electrical signal across the chest to estimate the volume of blood pumped out by the heart. It involves sticky pads attached to the neck and lower chest, and the electrical signal is too small to be felt by the participant. The second method is a measurement of the volume of blood leaving the heart using an ultrasound scan of the heart. Along with these established methods, two types of camera (a standard digital camera and a

thermal camera) are used to record the skin responses. With these monitors in place, two methods are used to artificially change the participants' heart function. Participants undergo a physical exercise using an exercise bike and cold pressor test where a hand is placed in cold water. The established methods are the camera images are

compared to see how well the cameras are at determining cardiovascular changes.

What are the possible benefits and risks of participating?
There are no direct benefits with participants. There are no notable risks with participating however participants may experience discomfort during the exercise or when they place their hand in cold water. If a previously undiagnosed problem is seen in the ultrasound, participants will be advised to see their general practitioner.

Where is the study run from?
Kadoorie Centre for Critical Care Research (UK)

When is the study starting and how long is it expected to run for?
July 2016 to August 2017

Who is funding the study?
NIHR Oxford Biomedical Research Centre (UK)

Who is the main contact?
Dr Mirae Harford
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
R45629/RE002 (Research and Development Reference 12056)

Study information

Scientific Title
Peripheral Perfusion and Stroke Volume Estimation using image based non-contact method compared to transthoracic echocardiography and thoracic bioimpedance monitoring

Acronym
PPSVE

Study objectives
Differential response of central and peripheral areas of the skin to cardiovascular changes can be detected from camera images.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1.Medical Sciences Inter-Divisional Research Ethics Committee, University of Oxford, United Kingdom, 07/07/2016, ref: R45629/RE002
2. Oxford University Hospitals NHS Foundation Trust - Trust Management Approval, 11/07/2016, ref: 12056.

Study design
Single-centre non randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Healthy volunteers

Interventions
This study has been designed to compare camera monitoring against two established methods of measuring cardiac output (amount of blood pumped out by the heart per minute). As this is a pilot/proof of concept study, it is carried out in healthy volunteers who would be expected to have normal responses to physical challenges such as exercise. Participants are sampled consecutively. This study has been designed to compare camera monitoring against two established methods of measuring cardiac output (amount of blood pumped by the heart per minute).

Two reference monitoring devices are used:
1) A bioimpedance monitor which works via four adhesive electrodes on the neck/lower chest (identical to electrodes used for electrocardiogram (ECG)) which records small bioelectrical impulses from the thorax to estimate the amount of fluid within the chest cavity,
2) A transthoracic echocardiogram (ultrasound of the heart) which involves a small ultrasound probe on the chest wall with small amount of gel between skin and the probe. These monitors are worn on the participants throughout the recording process (60 minutes) along with the camera monitor.

These methods have been chosen for their non-invasive nature as well as reported accuracy. Along with these established methods, two types of cameras (a standard digital camera and a thermal camera) are used to record the skin responses.

With these monitors in place, two methods are used to artificially change the participants' heart function; a physical exercise using an exercise bike and cold pressor test where a hand is placed in cold water. The monitors are recording the participant's physiological variables including: heart rate, stroke volume (amount of blood pumped out by the heart with each beat), cardiac output (amount of blood pumped out per minute). Monitoring is continued for 15 minutes after the end of the last challenge (cold pressor test). The entire duration of the study visit is expected to last approximately 90 minutes and each participant only attends one visit. There is no further follow up after this point.

Intervention Type
Other

Primary outcome measure
Changes between face to hand pulse transit time/skin colour change/skin temperature change is measured using a camera at baseline and throughout the recording period of 60 minutes, and compared to gold standard monitoring using a bioimpedance monitor.

Secondary outcome measures
1. Changes between Face to hand pulse transit time/Skin Colour change/Skin temperature change is measured using a camera at baseline and throughout the recording period of 60 minutes, and compared to gold standard monitoring using transthoracic echocardiogram
2. Stroke volume estimates throughout the recording period of 60 minutes are compared using the three methods: camera, bioimpedance monitor, transthoracic echocardiogram

Overall study start date
06/07/2016

Completion date
06/08/2017

Eligibility

Key inclusion criteria
1. Healthy volunteers
2. Age 18-60
3. Participant is willing and able to give informed consent for participation in the study.

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Male

Target number of participants
15

Total final enrolment
15

Key exclusion criteria
1. Patient whose anatomy, condition, or other required monitoring precludes the use of the camera equipment, transthoracic echocardiogram, or thoracic bioimpedance monitor kit. Examples include thoracic wall deformity not allowing transthoracic echocardiography. Equally, difficulty obtaining an adequate transthoracic echocardiography window due to breast tissue will be taken as a relative contraindication for enrolment
2. History of cardiovascular disease
3. Any current or previous leg injuries which precludes the use of a bicycle-like device

Date of first enrolment
25/08/2016

Date of final enrolment
31/05/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Kadoorie Centre for Critical Care Research
Kadoorie Centre for Critical Care Research
John Radcliffe Hospital
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
University of Oxford

Sponsor details
Clinical Trials and Research Governance
Joint Research Office
Block 60
Churchill Hospital
Old Road
Headington
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United Kingdom
OX3 7LE

Sponsor type
University/education

Website
https://www.admin.ox.ac.uk/researchsupport/ctrg/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Not defined

Funder Name
National Institute for Health Research

Funder Name
NIHR Oxford Biomedical Research Centre

Results and Publications

Publication and dissemination plan
It is anticipated that the project outcome will be written up for peer reviewed publication with possibility of being presented in conferences. The results may be shared internally within the department/university, and may be shared on a public website for Kadoorie Centre for Research which will be available to the public.
We will offer to contact any participants who express an interest in the result with the outcomes of the project.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study is not expected to be made available due to the data from camera cannot be anonymised (given that facial skin response recorded on camera is one of the outcome measures). In our ethics application this was extensively discussed and it was decided that the dataset will be held in a secure setting behind two locked doors and restricted access within Kadoorie Centre for Critical Care Research, John Radcliffe Hospital, Oxford, OX3 9DU.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/01/2019	22/04/2021	Yes	No
Results article		01/01/2021	22/04/2021	Yes	No