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Assessment of the agreement between the snap40 wearable device and accepted measuring techniques in high dependency and the emergency department

Submission date 12/07/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/07/2016	**Overall study status** Completed	
Last Edited 12/07/2016	**Condition category** Other	

Plain English summary of protocol

Background and study aims
It is widely recognised that the vital signs of a patient change before their condition worsens (deterioration). However, on general medical and surgical wards patient vital signs are often measured at specific times, rather than continuously. Existing continuous monitors are bulky, expensive pieces of equipment that anchor patients to bed. snap40 are developing a discreet wearable device that can be worn on the upper arm to continuously monitor patients, alerting healthcare staff automatically to patient deterioration while allowing complete patient mobility around the hospital. The aim of this study is to assess the difference between vital sign readings collected by snap40's wearable device and the current best method (gold standard) of monitoring vital signs, namely a Draeger intensive care monitor and nursing observations.

Who can participate?
Patients admitted to High Dependency Units (medical or surgical) and the Emergency Department between the ages of 18 and 85 who do not have any implanted electrical medical devices.

What does the study involve?
All participants continue to receive usual care in hospital, but also wear snap40’s wearable device on their upper arm, which consists of an armband with built-in sensors and a rechargeable battery. The device continuously monitors heart rate, respiratory (breathing) rate, blood pressure, oxygen saturations (how much oxygen is present in the blood), skin temperature, movement and perspiration. Patients also have these vital signs measured as usual, through a Draeger IACS intensive care monitor (heart rate, respiratory rate, oxygen saturations, blood pressure) and nursing observations (temperature and neurological status – nerve responses). At the end of the study, vital signs from the snap40 wearable device are compared to gold standard observations to assess the agreement of readings.

What are the possible benefits and risks of participating?
There are no direct benefits involved for those participating in this study. The snap40 armband is small and comfortable to wear so it should not cause discomfort. It doesn't break the skin and is non-invasive. Personal information about participants will be collected in this study but it will have any information that could identify individual patients removed (anonymised) before it leaves the hospital. The risk of privacy being breached is therefore very low.

Where is the study run from?
Victoria Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2015 to April 2017

Who is funding the study?
snap40 (UK)

Who is the main contact?
Mr Christopher McCann
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Study website
http://snap40.com

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.5

Study information

Scientific Title
SNAPGREE - A cross-sectional observational study in patients in high-dependency and the emergency department to assess the level of agreement between vital signs measured by the snap40 wearable device and gold standard techniques

Acronym
SNAPGREE

Study objectives
The snap40 wearable device is able to monitor vital signs within an allowable level of agreement to gold standard vital sign monitoring techniques.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Single-centre cross-sectional study

Primary study design
Observational

Secondary study design

Study setting(s)
Hospital

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
Vital sign monitoring

Interventions
Participants are sampled consecutively. Via a Draeger IACs intensive care monitor, participants will have gold standard vital sign measurements taken for blood pressure (via a BP cuff), heart rate (via ECG trace), respiratory rate (via impedance) and oxygen saturations (via pulse oximetry). These are collected on a second-to-second basis. Nursing staff will also collect tympanic temperature and neurological status via AVPU and GCS every hour. Participants will also wear the snap40 armband which collects, on a second-to-second basis heart rate, respiratory rate, blood pressure, oxygen saturation, temperature, movement and perspiration. There will be no follow up with participants.

Intervention Type
Other

Primary outcome measure
Agreement between vital signs calculated by the snap40 wearable device and accepted measuring techniques is measured by vital signs from the snap40 wearable device and from the Draeger IACs and nursing observations continuously throughout the study.

Secondary outcome measures
1. Agreement between the snap40 wearable device and accepted measurement techniques at high and low reading levels is measured by vital signs from the snap40 wearable device and from the Draeger IACs and nursing observations continuously throughout the study
2. Agreement in changes in readings over time between the snap40 wearable device and accepted measurement techniques is measured measured by vital signs from the snap40 wearable device and from the Draeger IACs and nursing observations continuously throughout the study
3. Agreement between the calculation of a National Early Warning Score (NEWS) from readings taken by the snap40 wearable device to a NEWS score calculated from accepted measurement techniques is measured measured by vital signs from the snap40 wearable device and from the Draeger IACs and nursing observations continuously throughout the study

Overall study start date
01/10/2015

Completion date
30/04/2017

Eligibility

Key inclusion criteria
1. Aged between 18 and 85
2. Male or female
3. Patients from either medical or surgical high dependency or from the emergency department

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
170

Key exclusion criteria

1. Patients with implantable defibrillators, pacemakers or neurostimulators
2. If there is a difference in blood pressure between arms of greater than 10mmHg (measured at time of recruitment)

Date of first enrolment
01/08/2016

Date of final enrolment
31/10/2016

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Victoria Hospital
Hayfield Road
Kirkcaldy
United Kingdom
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Sponsor information

Organisation
snap40

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
snap40

Results and Publications

Publication and dissemination plan
Publication is planned in a high-impact peer reviewed journal within a year of the study completing.

Intention to publish date
31/10/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date