

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/07/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/07/2016	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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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Contact information

Type(s)

Public

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Other

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(s)

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.

Key secondary outcome(s)

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 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 by vital signs from the snap40 wearable device and from the Draeger IACs and nursing observations continuously throughout the study

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

Scotland

Study participating centre

Victoria Hospital
Hayfield Road
Kirkcaldy
United Kingdom
KY2 5AH

Sponsor information

Organisation
snap40

ROR
<https://ror.org/03a2dk673>

Funder(s)

Funder type
Industry

Funder Name
snap40

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes