Feasability Assessment of wearable sensors for continuous ambulatory vital signs monitoring

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON48983

Source
ToetsingOnline

Brief title
Vital signs monitoring with wearable sensors

Condition

- Other condition

Synonym
Not applicable

Health condition

Dit betreft een validatie studie van continue metingen van vitale functies, welke niet gerelateerd is aan een enkele aandoening of orgaansysteem

Research involving
Human

Sponsors and support

Primary sponsor: Divisie Vitale Functies
Source(s) of monetary or material Support: Europese Commissie 'Horizon2020' subsidie

Intervention

Keyword: deterioration, validation study, vital signs, wireless monitoring

Outcome measures

Primary outcome

Study 1

Primary outcome is the accuracy of the vital sign parameters that each

prototype solution measures as compared with the reference standard.

Study 2

The primary outcome measure of study 2 is the usability of each of the

prototype solutions, as measured with the system usability scale (SUS).

Secondary outcome

The secondary outcome measure of study 2 is the technical feasibility of

ambulatory monitoring at home, which will be evaluated with the following

metrics:

* Success rate of data transmission to external server or gateway device,

calculated as percentage: [(actual data points captured / intended data points)]

o Duration of interrupted monitoring episodes (e.g., data gaps of 15 minutes, 1

hour, 8 hours or more)

o Frequency of interrupted monitoring episodes (e.g., data gaps)

o The level of accessibility of the measured data

Study description

Background summary

Hospital in-patients have regular vital signs monitoring to detect clinical deterioration. On general wards this would be expected to be every 8 hours. Due to the intermittent nature of this monitoring early signs of deterioration may be missed and as such, patient deterioration is detected too late or not at all. This is particularly so as patients are now often more frail, elderly, with multiple co-morbidities and polypharmacy. Treatments are also getting more aggressive (e.g. chemotherapy for cancer). Data from across Europe points to undetected deterioration being one of the biggest patient safety challenges facing modern healthcare. Therefore, there is a huge unfulfilled need for better monitoring of vital signs and other data to identify deterioration earlier and to alert the appropriate personnel. The increase pressure on health care systems to discharge patients to the community now means vital signs monitoring is becoming relevant in the home setting.

Within the *Nightingale* project, five leading European academic hospitals (UMC, Utrecht, the Netherlands; Karolinska, Stockholm, Sweden; University College London Hospitals, London, United Kingdom; University Hospital Leuven, Belgium and University Hospital Aachen, Germany) use the European commission*s Pre-commercial Procurement (PCP) funding scheme to challenge and stimulate European industry to develop a monitoring system to wirelessly connect patients and carers to detect deterioration early, be it in the hospital or the home.

As a result, four industrial suppliers have been selected to build early prototypes for wireless patient monitoring on the general ward and at home after discharge. If validated, these sensors may provide early detection of patient deterioration enabling more timely and appropriate intervention within the near future.

Study objective

The primary objective is to study whether the (early prototype) sensors are able to reliably measure the vital signs they are designed to record.

The secondary objective is to determine the feasibility and user acceptance of the (early prototype) sensors when tested at home during daily (freely moving) activities.

Study design

This protocol describes two substudies that will each address one objective as described above:

* Study 1 is a methods comparison study in healthy volunteers. It is designed to assess the accuracy of the sensors. Participants* vital signs will be recorded from the prototype sensors for 2 hours each. During each 2h session vital signs from the sensors will be compared with the vital signs recorded using a CE marked, ICU-grade patient (wired) monitoring system.

* Study 2: comprises a feasibility study in which volunteers will wear the (early) prototype sensor for a period of five days during their normal daily activities, both in their home and outside. During a month, volunteers will wear another sensor every week (from Monday till Friday). The order in which a participant wears one of the four prototype sensors will be rotated.

Study burden and risks

Both the methods comparison study (Study 1) and feasibility testing at home (Study 2) will be performed with healthy volunteers which do not need routine monitoring.

Intended application: the four prototype sensors are:
1.) and 2.): adhesive patch sensors placed on the patient*s chest,
3.) an upper-arm sensor
4.) a soft flexible chest strap.

These positions allow measuring vital signs without the inconvenience of physical attachment to immobile monitoring systems. All sensors are lightweight, wireless (no need for cables), and allow untethered measuring of vital signs while in bed, at home or potentially anywhere. As with any adhesive plaster/tape, it is possible that some volunteers will experience skin irritation in response to the adhesives or textiles used, in which case the sensor will be removed. To prevent any skin irritation, we will ensure that a participant does not wear two 'patch' sensors in sequence. Since physical discomfort from the sensors is unlikely, volunteer burden is minimal

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Study 1
10 volunteers of both sexes (*18 years of age) are eligible for enrolment, with the following criteria:
* 5 volunteers need to be at age 65 or above
* 3 volunteers need to have a BMI >30 kg/m2, Study 2
10 volunteers (*18 years of age) are eligible for enrolment, with the following criteria:
* At least one hospitalization requiring monitoring in the past two years (*former patients*)
* Currently healthy or in a stable phase of chronic illness
* 3 volunteers need to have a BMI >30 kg/m2
* 3 volunteers need to live alone (without informal carer)

Exclusion criteria

* Known allergy/skin irritation to the adhesives used in the sensor patches.
* Implanted active medical devices, such as a cardioverter defibrillator or a pacemaker
* Current pregnancy

* Inability to give informed consent

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2019
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	1) The Patch;2) The Checkpoint Cardio sensor 3) Emfit 247 4) Sentinel biosensor
Registration:	No

Ethics review

Approved WMO

Date:	06-03-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date:	03-06-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL67031.041.18

Study results