Clinical validation of vital signs measured by the Vital Signs Monitoring System in a controlled environment

Published: 20-12-2021
Last updated: 25-03-2025

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Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON50709

Source
ToetsingOnline

Brief title
Clinical validation of vital signs monitoring

Condition

- Other condition

Synonym
n/a

Health condition

n.v.t.

Research involving
Human

Sponsors and support

Primary sponsor: FastFocus B.V.
Source(s) of monetary or material Support: bedrijf FastFocus B.V.

Intervention

Keyword: medical device, oxygen saturation, vital signs, wireless monitoring

Outcome measures

Primary outcome

The primary outcome is the accuracy of the device under investigation to

determine functional oxygen saturation as compared to a reference device and to

determine respiratory rate as compared to visual observations.

Secondary outcome

The secondary outcome is the accuracy of the device under investigation to

determine respiratory rate compared to a reference device.

Study description

Background summary

Current general ward monitoring protocols typically consist of intermittent spot checks by a nurse about every 4*8*h. Changes in vital signs are a warning sign of clinical deterioration, which are not always noticed by the spot checks. To provide healthcare professionals with a method to frequently monitor vital signs, FastFocus developed its second generation of a wireless monitoring system, the Vital Signs Monitoring System. This wearable device combines physical activity monitoring with the monitoring of vital signs and is, therefore, feasible to be used on ambulant patients in a healthcare environment. We want to evaluate the accuracy of the Vital Signs Monitoring System to determine functional oxygen saturation and respiratory rate in a clinical investigation. This is essential to assure its accuracy before bringing the device to the market.

Study objective

The main objectives of this study are to determine the accuracy of the device (1) to determine functional oxygen saturation (SpO2) compared to a reference device, and (2) to determine respiratory rate compared to visual observations. As a secondary objective, the measured respiratory rate will be compared to a reference device.

Study design

This study is a method-comparison study in a controlled environment. Healthy volunteers will perform a controlled desaturation procedure and controlled respiratory rate procedure while being monitored by the device under investigation and a reference device. The respiratory rate will be observed visually.

Intervention

The subjects will undergo a controlled desaturation procedure and respiratory rate procedure. Total participating time is approximately 2.5 hours (excluding breaks between measurements).

Study burden and risks

Brief and profound hypoxia is well tolerated by healthy humans. Subjects might experience a physical reaction to decreased oxygen saturation levels or hyperventilation or other symptoms during increased respiratory rates. However, these symptoms are reversible. In addition, subjects can stop at any moment when they do not feel well. The subjects need approximately 2.5 hours to participate in the study. Although, subjects will not experience any personal benefit from participating in the study, their participation can help improve the device which future patients can benefit of. The hardware of the device under investigation is identical to another FastFocus device that is CE marked as a medical device. In summary, it is concluded that the risk and burden for participating in the study are low.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Aged 18 to 50 years old
- ASA category 1: a normal healthy subject. Example: fit, nonobese (BMI under 30), non-smoking with good exercise tolerance
- No hypertension

Exclusion criteria

- Inability to give informed consent
- At risk during hypoxia due to medical conditions (e.g. cardiovascular or pulmonary disease)
- Pregnant or braestfeeding

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	31-01-2022
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Vital Signs Monitoring System
Registration:	No

Ethics review

Approved WMO

Date:	20-12-2021
Application type:	First submission
Review commission:	METC NedMec

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	NL78971.000.21

Study results

Date completed:	24-02-2022
Results posted:	27-12-2022

First publication
17-11-2022

URL result
URL
Type
int
Naam
M2.2 Samenvatting voor de leek
URL

Internal documents
File