Automated spot-check respiration and pulse monitoring for 5-18 year old patients

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

Summary

ID

NL-OMON40772

Source
ToetsingOnline

Brief title
Accelerometry for Vital Signs Measurement (AVSM)

Condition

- Other condition

Synonym
monitoring, signals

Health condition

vital signals monitoring

Research involving
Human

Sponsors and support

Primary sponsor: Philips Research
Source(s) of monetary or material Support: Philips Electronics Nederland

Intervention

Keyword: Pulse rate, Respiration Rate, Thoracic motion, Vital signals

Outcome measures

Primary outcome

Primary objective:

The primary objective is obtaining motion sensor data for performance validation of a respiration rate and pulse rate monitoring algorithm for use on 5-18 years old patients.

The data collected using the motion sensor of this study will be compared with the one obtained using the golden standard for respiratory frequency (by using a respiration band) and heart rate (by using ECG) .

Secondary outcome

The secondary objective is obtaining motion sensor data for the development and improvement of respiration rate and pulse rate detection algorithms specific for 5-18 years old patients.

Study description

Background summary

Hospital scoring systems like the Early Warning Score (EWS) offer a simple guide for nursing & medical staff to quickly determine the degree of illness of a patient by combining their vital signs into one single composite score. It has been shown that using such scoring system on general wards can reduce the number of unexpected intensive care admissions by 70% thanks to early detection

of patient deterioration. On pediatric wards, the use of Pediatric Early Warning Scoring (PEWS) has the potential to greatly enhance patient safety. The patient*s heart rate and respiration rate are two of the vital signs that are included in the PEWS system. Measuring these parameters from 5-18 years old patients multiple times a day requires significant nurse effort, patience of the patient (sit still during counting) and/or involves wired monitoring. A method that would allow getting an automated reading on both the heart rate and respiration rate in a wireless and unobtrusive manner would make the life of both nurses and patients easier and more comfortable, while improving the patient*s safety by monitoring their vital signs.

Study objective

This clinical investigation is designed to evaluate whether respiration rate and heart rate from pediatric patients (5-18 years) can be measured accurately using thoracic motion data
This study is designed to collect data for testing of the respiration rate and pulse rate detection algorithm, implemented in the Philips IntelliVue CL Respiration Pod, for use with 5-18 years old patients. The data collected using the motion sensor of this study will be compared with the one obtained using the golden standard for respiratory frequency (by using a respiration band) and heart rate (by using ECG) .

Study design

A total number of two investigational devices will be used in this study. These are: the Respiration pod prototype with the datalogger and the slightly modified transducer band. The Respiration pod prototype contains the motion sensors, while the datalogger stores the acquired data from the motion sensors, transducer band and ECG. The transducer band is a slightly modified version of a commercially available, CE-approved device. The modification concerns the connection of pressure studs for connecting the band to the datalogger.

Study burden and risks

Wearing the measurement apparatus may cause some discomfort.

All risks are mitigated to acceptable levels.
Further information can be found in the chapter 11 of the Research protocol.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Patients of MMC- pediatric department
-Age between 5 and 18 years old
-Subjects must be able to provide an informed consent or have legally authorized representative consent to participate
-Subjects of 12 years and older must provide assent to participate
-Subjects are hospitalized patients of the pediatric department of MMC and stay there for at least 24 hours.

Exclusion criteria

Exclusion criteria for subject selection
* Subjects with deformations that prevent proper device positioning
* Subjects with arrhythmia
* Subjects who had rib surgery
* Subjects with skin irritation that prevent 24 hours wearing the device
* Subjects having implants or devices connected that might be affected by the bioimpedance

measurement.

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):	20-03-2015
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	29-12-2014
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL49822.015.14