A PHASE 0, NON-INTERVENTIONAL, NON-INVESTIGATIONAL MEDICINAL PRODUCT, EARLY TECHNOLOGY EXPLORATION STUDY WITH CONNECTED DIGITAL DEVICES FOR SEMI-CONTINUOUS COLLECTION OF VITAL SIGNS IN A HEALTHY PEDIATRIC POPULATION.

Published: 27-11-2018
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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON46008

Source
ToetsingOnline

Brief title
Pediatric vital signs collection study in children.

Condition

- Other condition

Synonym
Not applicable.

Health condition

Niet van toepassing

Research involving
Human

Sponsors and support

Primary sponsor: Janssen Cilag International
Source(s) of monetary or material Support: Farmaceutische Industrie.

Intervention

Keyword: Comparison study, Vital Signs

Outcome measures

Primary outcome

To compare Leman Micro Devices, health sensing solution for smartphones (LMD)

with gold standards for vital signs assessments

To compare Isansys Lifetouch Smart Patch Cardiac Sensor with Patient Status

Engine (LSP) with gold standards for vital signs assessments

Secondary outcome

To evaluate the engineering support of LMD

Study description

Background summary

Measuring vital signs in young children participating in medical-scientific studies is often time consuming, e.g., because of frequent visits to a doctor or clinic, and can be stressful for the child and its parents. The ability to monitor the vital signs using a simple technology connected to digital devices can alleviate stress for both the child and its parents. It can also result in the possibility to monitor the situation of a child when outside the hospital

setting.

The Sponsor is investigating the possibilities to use 2 combinations of technologies for easier monitoring of vital signs.

LSP/NWO
The LSP system consists of is 2 adhesive plasters, 1 on the front of the chest and 1 in the armpit, with sensors. The NWO system is a wristband with a sensor over a finger. The sensors relay the measurements to an app on a tablet.

MSB/OSS
The MSB is a button that is attached to the child*s clothes that measures activity and respiratory frequency. It is combined with the OSS which is an elastic sock with a sensor. Both devices are connected to a mobile phone which collects.

Study objective

The purpose of this study is to investigate how well 2 combinations of devices for continuous monitoring of vital signs (in this case pulse rate, breathing frequency, peripheral oxygen saturation [SpO2], and skin temperature) work when used in healthy children aged 0 to 36 months. The systems used are:

• the Isansys Lifetouch Blue Continuous Cardiac Sensor and Lifetemp Continuous Clinical Thermometer with Patient Status Engine (LSP) combined with the Nonin WristOx2® Pulse Oximeter Model 3150 (NWO)
• a combination of MonBaby Smart Button (MSB) and Owlet Smart SockTM (OSS).

Both combinations and the individual systems, are compared with the current standards for measuring vital signs in this age group.

It will also be investigated how easy the systems are to use and what the impression is about the acceptance of the system used by the child.

Study design

We will first evaluate whether the child may participate. The responsible doctor will perform a short physical examination, and will measure the number of breaths per minute, heart rate, SpO2 and body temperature. The responsible doctor will also ask about the medical history of the child. These factors are important for the study because they can influence the results of the measurements.

The actual study will consist of measurements that will be performed during a period of 2 hours.

Whether the measurements will be performed using the LSP/NWO combination or the MSB/OSS combination will be determined by chance. Ten children will be monitored using the LSP/NWO combination and 10 using the MSB/OSS combination, meaning that you will have 50% chance to have either one of the systems.

During the study, the following will take place:
• We will ask about the wellbeing of the child and if there are details about his/her health
• We will do a physical examination
• We will measure the vital signs of the child
• We will ask to complete a questionnaire about how the parent and the child feel about the measuring methods used.

Study burden and risks

The LSP systems and the standard method use adhesive plasters which may lead to skin irritation (rash and itching) during or after use.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

healthy children
0 - 36 months

Exclusion criteria

Previous participation in the current study.
The subject is participating in drug interventional studies.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-11-2018
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	27-11-2018

Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	NL67641.056.18