Exploration of SpO2 probe for low resource settings

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

Summary

ID

NL-OMON42710

Source
ToetsingOnline

Brief title
Diagnostics solutions for low-resource settings

Condition

- Other condition
- Respiratory tract infections

Synonym
nvt

Health condition

geen aandoening, onderzoek met gezonde deelnemers

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Low resource settings, Oxygen saturation, Pneumonia

Outcome measures

Primary outcome

Primary endpoint is achieved when the signal strength for each probe (belly, forehead, finger, and heel) in each age category (0-2 months, 2-36 months, and 36-60 months) is determined in order to compare the signal strength with our reference value from the null-hypotheses H0: the signal strength is 0.4%. The signal strength is defined as the pulse height of the infrared light divided by its slowly-varying baseline.

Secondary outcome

The secondary endpoint is achieved when the user aspects per probe and age group are determined to a level that any frequently occurring disadvantage of a probe would be identified.

Study description

Background summary

Pneumonia is the leading cause of death in children under the age of 5. Rapid breathing is one of the signs of pneumonia, but this is often not enough to correctly asses the disease. Determining the level of the oxygen saturation can help confirm and assess the severity of the disease and take better treatment decisions.

Study objective

The primary objective of the study is to explore and compare the signal strength of different probes for measuring pulse oximetry signals on different body locations. The secondary objective of the study is comparing aspects of user experience (via observations and interviews) of different pulse oximeter probes on healthy children from 0 to 5 years.

Study design

This study is designed as a data collection and observational study. Different probe designs, technologies and body locations are tested.
After the intake and the informed consent procedure, the child is weighed to select the reference probe. A camera will be set to obtain a good view of the subject and the reference probe will be attached to the child*s finger. The new-design probe will be attached to the child; the data will be collected for 5 minutes. The new-design probe will be removed and the procedure will be repeated until all new-design probes are tested. The order of the probes will be randomized with every subject. On six of the 36 subjects only mock-ups will be tested on user experience and one size fits all aspect of the mock-up.

Study burden and risks

In the study there is no benefit for the subjects. There is future benefit to the study population, although in low resource settings. When future population receives the right diagnosis and applicable treatment of the disease, this will result in saving their lives.
The risks associated with participation in this study can be considered negligible since all potential risks, including electrical hazards which may come from parts/devices of the setup, and cross-contamination, are properly mitigated. Also, the burden can be considered minimal, since the sensors are developed in such a way they are safe and minimally invasive. The aim of the study is to collect data on PPG signals from young children of 0-5 years old and to develop a single sensor for this age category. The study will also gain insights in usability of the sensor and the body location of the measurement. Hence, the study can only be carried out with this target group, since their behaviour and body characteristics are clearly distinct from other age groups.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Healthy children between 0 - 5 years, Indian and African heritage would be preferred but not mandatory, since the probe would be targeting India and Africa.

Exclusion criteria

Subjects carrying or wearing any supportive or medical device in the area that the probe is going to be placed or subjects missing or with a physical deformity in that extremity (feet or finger).
Subjects with childhood asthma, cardiovascular diseases, heart murmur or any type of medication (excluding medication without a prescription).

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):	24-09-2015
Enrollment:	36
Type:	Actual

Medical products/devices used

Generic name:	Nellcor Forehead SpO2 Sensor with OxiMax Technology and D-YS NellcorTM sensor finger probe
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	29-07-2015
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	04-09-2015
Application type:	Amendment
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	NL54092.015.15