Early Feasibility Data Collection using ClearSight on Children Less than Two Years Old.

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

Summary

ID

NL-OMON56297

Source
ToetsingOnline

Brief title
ClearSight Baby Cuff

Condition

- Other condition

Synonym
n/a, Non invasive blood pressure monitoring

Health condition

N/A, measurement of blood pressure with a finger cuff

Research involving
Human

Sponsors and support

Primary sponsor: Edwards Lifesciences LLC
Source(s) of monetary or material Support: Edwards LifeSciences

Intervention

Keyword: Blood Pressure Monitor, ClearSight, Infants, Non-Invasive

Outcome measures

Primary outcome

As the study is an early feasibility data collection, the primary outcome of

the study is the confirmation that the design works and is able to measure

blood pressure continously and non-invasively in children 0-2 years old.

Measurement accuracy is determined by comparing the ClearSight blood pressure

reading to a standard blood pressure reading.

Secondary outcome

Aspects such as ease of use will also be evaluated

Study description

Background summary

It has been possible for some time to continuously measure blood pressure in adults with a cuff around a finger (ClearSight technology, Edwards LifeSciences). An advantage of this measurement is that it is possible to monitor a patient's blood pressure continuously, rather than with an upper arm cuff that inflates once every few minutes. Another advantage is that it is not necessary to give an extra injection to place a catheter in the artery of the wrist.

In young children (0-2 years old) this method of measurement is not yet available. Recently, the company Edwards LifeSciences (Irvine, CA, USA) developed prototype cuffs that can be applied in children 0-2 years old. The principle of operation and the materials used are identical to the standard cuffs used in adults. About 10 years ago, a first exploration was made of

measurements with a cuff around the finger in children (please refer to section K4-Scientific Papers in the Reseach file). No safety risks were observed during these measurements. The current prototype cuffs have now been developed based on this earlier experience.

The current study is an exploration of the feasibility of the design of newly developed prototype cuffs in children 0-2 years. The data will be used to estimate the feasibility of a larger follow-up study at a later stage.

Study objective

In this study, we to confirm the cuff design and make sure it works. Aspects such as safety and ease of use are also evaluated.

Study design

This Study is a prospective, single-arm, observational data collection Study at 1 Study site in the Netherlands to evaluate a prototype ClearSight finger cuff in pediatric patients under 2 years of age

The examination takes approximately 30 minutes.

Step 1: The researcher, a doctor from the AMC, selects the child.

Step 2: The parent/legal representative gives permission to the researchers to carry out the measurements. At any time, without giving reasons, a parent/carer can decide to stop the study.

Step 3: Measurements will be taken with the prototype cuffs during anesthesia for the child's planned surgery. The blood pressure is measured with a cuff around a finger (index finger, middle finger, ring finger) in a period of up to 30 minutes. Anesthesia will not be changed or extended for this study. During this time, cuffs may be changed and the cuff may be tested on different fingers.

In addition to the researcher from the AMC, a researcher from Edwards Lifesciences can be present at the measurement.

During the examination, the child will receive standard care. No post-checks are necessary.

Study burden and risks

Blood pressure is measured on the finger for a limited time and under anesthesia for a planned surgery in a setting where the investigator is present at the measurement, therefore there is no real burden and additional risk

involved. Cf. E9 for a list of risks and mitigations.

Contacts

Public
Edwards Lifesciences LLC

One Edwards Way 1
Irvine, California 92614
US
Scientific
Edwards Lifesciences LLC

One Edwards Way 1
Irvine, California 92614
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Babies and toddlers (28 days-23 months)
Newborns

Inclusion criteria

Children in the age 0-2 years during anesthesia for a planned surgery

Exclusion criteria

1. Any significant disfigurement or prior injury to a participant*s finger that is intended to be used for monitoring with the prototype finger cuff
2. Inability to place finger cuffs appropriately due to subject anatomy,

condition, or obstructive paraphernalia
3. Known sensitivities to system materials
4. Broken or open skin located at the site of the finger cuff
5. Proven left*right difference in blood pressure
6. Cardiac problems that can cause a difference in blood pressure between the two arms, including aortic coarctation
7. Extreme contraction of the smooth muscles in the arteries and arterioles of the lower arm and hand, such as may be present in patients with Raynaud*s disease

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	10-01-2024
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	ClearSight Finger cuff
Registration:	No

Ethics review

Approved WMO

Date:	16-11-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL85126.018.23