Immediate Stimulation to Prevent and Inhibit cardiorespiratory Events in preterm infants

Published: 11-06-2021
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Evaluate the safety and feasibility of providing automated tactile stimulation in response to apnea, bradycardia and/or desaturation using the BreatheBuddy.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neonatal respiratory disorders
Study type	Interventional

Summary

ID

NL-OMON50955

Source
ToetsingOnline

Brief title
InSPIRE

Condition

- Neonatal respiratory disorders

Synonym
apnea, respiratory pause

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiorespiratory events, Preterm infant, Tactile stimulation

Outcome measures

Primary outcome

Safety and feasibility measures. Primary outcome will be the success in

providing automated tactile stimulation using the BreatheBuddy.

Secondary outcome

N/A

Study description

Background summary

Most preterm infants have difficulties breathing on their own, resulting in apnea, bradycardia and/or hypoxia. Despite preventive therapies, some infant often require adequate reactive intervention of the nurse in the form of tactile stimulation. In the current situation, the duration of apnea, bradycardia and hypoxia fully relies on the response time of the nurse. Our general hypothesis is that automated mechanical stimulation will shorten apnea, hypoxia and bradycardia by enabling a direct response. To test this hypothesis we designed the BreatheBuddy, a mechanical stimulation system for preterm infant that automatically responds to cardiorespiratory alarms of the patient monitor.

Study objective

Evaluate the safety and feasibility of providing automated tactile stimulation in response to apnea, bradycardia and/or desaturation using the BreatheBuddy.

Study design

a prospective randomized cross-over pilot study at the Neonatal Intensive Care Unit of the Leiden University Medical Center.

Intervention

Preterm infants will receive automated mechanical tactile stimulation from the BreatheBuddy in response to cardiorespiratory events.

Study burden and risks

The infant participating in this study will be exposed to minimal risk. However, because of their vulnerable stat we will closely monitor the effects and (unforeseen) side effects of the BreatheBuddy. There are potential benefits, but a larger RCT is needed to confirm this.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Premature newborns (<37 weeks pregnancy)

Inclusion criteria

Born between 24 weeks 0 days and 29 weeks and 6 days gestation.

Receiving non-invasive respiratory support (NCPAP or NIPPV).
Occurrence of apnea, bradycardia or desaturation of >10 seconds > 1 per hour, but otherwise clinically stable.
Expected to complete the 48-hour period with non-invasive respiratory support.
Written informed parental consent.

Exclusion criteria

Major congenital anomalies that have an adverse effect on breathing or ventilation.
Suspected or proven sepsis
Comfort score >14; comfort is scored by a nurse on 6 items with a 5-point Likert scale. When the sum of these scores is >14 the patient is experiencing discomfort which requires the nurse to look for the cause and, in case it does not improve, provide pain medication.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-07-2021
Enrollment:	16
Type:	Actual

Medical products/devices used

Generic name:	BreatheBuddy
Registration:	No

Ethics review

Approved WMO Date:	11-06-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	14-01-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 29343
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL77214.058.21
OMON	NL-OMON29343