Immediate Stimulation to Prevent and Inhibit cardioRespiratory Events In preterm infants

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It is safe and feasible to provide direct automatic mechanical tactile stimulation with the BreatheBuddy in preterm infants with frequent cardiorespiratory events

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29343

Bron
Nationaal Trial Register

Verkorte titel
InSPIRE

Aandoening

Apnea of prematurity

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Safety and feasibility of applying direct automatic mechanical tactile stimulation using the

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: 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.
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.
Study population: Preterm infants that are admitted to the NICU in Leiden. We will include 2 groups of infants with a different gestational age range, starting with 8 infants of 27-30 weeks gestation, followed by 8 infants of 24-27 weeks gestation.
Intervention: Preterm infants will receive automated mechanical tactile stimulation from the BreatheBuddy in response to cardiorespiratory events.
Main study parameters/endpoints: Safety and feasibility measures. Primary outcome will be the success in providing automated tactile stimulation using the BreatheBuddy.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The infant participating in this study will be exposed to minimal risk. However, because of their vulnerable state 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.

Doel van het onderzoek

It is safe and feasible to provide direct automatic mechanical tactile stimulation with the BreatheBuddy in preterm infants with frequent cardiorespiratory events

Onderzoeksopzet

2x 24 hours

Onderzoeksproduct en/of interventie

Providing direct automatic mechanical tactile stimulation with the BreatheBuddy in response to cardiorespiratory events indicated by the alarm lights.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Born between 24 weeks 0 days and 29 weeks and 6 days gestation.
- First 8 infants: gestational age between 27 weeks and 0 days and 29 weeks and 6 days gestation at start study.
- Last 8 infants: gestational age between 24 weeks and 0 days and 26 weeks and 6 days gestation at start study.
- Receiving non-invasive respiratory support (NCPAP or NIPPV).
- Occurrence of apnea, bradycardia or desaturation of >10 seconds > 1 per hour, but otherwise clinically stable. This can be defined by clinical alarms of the patient monitor and notes of the nurse.
- Expected to complete the 48-hour period with non-invasive respiratory support.
- Written informed parental consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2021
Aantal proefpersonen:	16
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	18-06-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50955
Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9606
CCMO	NL77214.058.21
OMON	NL-OMON50955

Resultaten