Effects of closed-loop automatic control of inspiratory fraction of oxygen (FiO2-C) on outcome of extremely preterm infants-a randomized controlled parallel group multicenter trial for safety and efficacy.

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To compare the effect of FiO2-C in addition to manual adjustments, in comparison with manual adjustments of FiO2 only, on death and severe complications of prematurity thought to be related to hypoxia/hyperoxia and neurodevelopmental impairment in...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON54702

Source
ToetsingOnline

Brief title
FiO2-C Trial

Condition

- Other condition

Synonym
prematurity

Health condition

vroeggeboorte

Research involving
Human

Sponsors and support

Primary sponsor: University Hospital Tübingen
Source(s) of monetary or material Support: 2.500.000

Intervention

Keyword: Closed-loop, Outcome, Oxygen, Preterm

Outcome measures

Primary outcome

Composite outcome of death, severe retinopathy of prematurity (ROP), chronic lung disease or necrotizing enterocolitis until 36 weeks PMA (or, for ROP, until full vascularization of the retina).

Composite outcome of death, language/ cognitive delay, motor impairment, severe visual impairment or hearing impairment at 24 months corrected age.

Secondary outcome

Individual components of the primary outcome variables and developmental scores of the Bayley Scales of Infant Development (3rd edition)

In selected centers only: time within the oxygen saturation target range, median FiO2, number of manual FiO2 adjustments, time of regional cerebral oxygenation within target range, cerebral volumes and brain injury by MRI at term equivalent age.

Study description

Background summary

Extremely low gestational age neonates (ELGAN; born below 28 weeks gestational age) frequently experience intermittent hypoxic/hyperoxemic episodes. Observational data indicate that severe and prolonged hypoxemic episodes are associated with rethinopathy of prematurity (ROP) impaired long-term development and death. Closed-loop automated control of the inspiratory fraction of oxygen (FiO2-C) reduces time outside the oxygen target range, decreases number and duration hypo- and hyperoixemic episodes and reduces caregivers workload. However effects of automated adjustments of FiO2 on short-term and long-term outcome of preterm infants are not known.

Study objective

To compare the effect of FiO2-C in addition to manual adjustments, in comparison with manual adjustments of FiO2 only, on death and severe complications of prematurity thought to be related to hypoxia/hyperoxia and neurodevelopmental impairment in extremely preterm infants. The primary outcome measure will be a composite of death, severe ROP, chronic lung disease, or necrotizing enterocolitis until a postmenstrual age of 36 weeks or until complete vascularization of the retina, respectively. Key secondary outcome variables are death or major neurodevelopmental impairment determined at 24 months corrected age and the individual components of the primary outcome, the developmental scores of the Bayles Scales (3rd Edition) and brain unjiry on cerebral ultrasound or MRI at term. Safety analyses will assess adverse events and complications of prematurity.

Study design

Partially observer blinded, randomized, controlled, multicenter parallel group comparison for superiority.

Intervention

Experimental intervention:
Application of FiO2-C (provided by standard infant ventilators) in addition to manual adjustments of the inspired oxygen fraction (FiO2) during mechanical ventilation and continuous positive airway pressure (CPAP) in extreme preterm infants at least up to 32weeks PMA (or discharge from hospital) according to a standardized protocol.
Control intervention:
Standard care, i.e. manual adjustments of the FiO2 only

Study burden and risks

Burden is minimal. An extra adhesive band to measure saturations has to be strapped around foot or hand.
Minimal risk. Based on earlier evidence it is not to be expected that -with using automated inspired oxygen control by ventilator- a higher amount saturations will be outside of the targeted range.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Premature newborns (<37 weeks pregnancy)

Inclusion criteria

Preterm infant born at gestational age 24-28 weeks

Exclusion criteria

Palliative care Congenital anomalies Postnatal age >48 hours No parental consent No device with automatic FiO2 control

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2019
Enrollment:	150
Type:	Actual

Medical products/devices used

Generic name:	Closed-loop oxygen control
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	20-03-2019
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	15-08-2019

Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	02-12-2019
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	27-06-2023
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
ClinicalTrials.gov	NCT03168516
CCMO	NL65766.015.18