Pain observation using Skin Conductance measurement as compared to Comfortneo scale on newborn with respiratory support.

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A:To get insight whether respiratory support in the neonatal population, as artificially ventilation and Nasal Continously Positive Airway Pressure, will give an increased stress or pain respons which only can be detected by a 24 hours SCA...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Neonatal and perinatal conditions
Study type	Observational non invasive

Summary

ID

NL-OMON39224

Source
ToetsingOnline

Brief title
Skin Conductance measurement and pain in neonates

Condition

- Neonatal and perinatal conditions

Synonym
newborn, pain

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: neonates, pain, Skin Conductance measurment

Outcome measures

Primary outcome

Frequency and intensity of pain response en pain sensation by Skin Conductance

measurement.

Correlation between SCA and Comfortneo scale in pain response.

Secondary outcome

Continous measurement of heart rate, bloodpressure, oxygen saturation,

respiration and temperature.

Study description

Background summary

In the neonatal intensive care unit (NICU) newborns frequently are submitted to painful procedures like blood sampling by heellances, endotracheal suctioning and inserting tubes. It is well known that newborns demonstrate an increase sensitivity of pain which may affect clinical or neurodevelopment outcomes. So it is important to detect pain early and start a treatment. Detection of pain in this patient group is difficult because of the inability of verbal expression, the weak muscle structure to express in behavioural response and the vulnerable physiological response. Pain behaviour observation scales (as Comfortneo scale, Neonatal Infant Pain Scale, Premature Infant Pain Profile, Cries) are used to observe distress and pain and start pain management conform the protocol. Although these are valid behavior observation scales, there is still a subjective interpretation.
A skin conductant algesi meassure (SCA) is a valid method to evaluate pain and distress in newborn on changes in skin conductance caused by nociceptive incentives induced by emotional palmar and plantar sweating in 1-2 seconds due to symphatic nerve activity. An increase in the number of fluctuations and an increase of the baseline on the screen can be interpreted as a pain response. Roeggen et al (2012) established a baseline of SCA activity in hospitalised

infants at rest (1). This can be used as a reference in our study.
L. Pareira da Silva (2011) concluded that the SCA is able to differentiate nociceptive pain response to acute pain of different durations such as a heellance for bloodgas analysis(longer duration) and heellance for glycaemia analysis (short duration time) (2). Although the NIPS score and the SCA peaks were both increased, significant higher SCA area under low peaks index were only registered when blood was drawn for blood gas analysis.
Gjerstad et al (2008) showed that the number of SCA fluctuations during endotracheal suctioning in artificially ventilated children between 1 day and 11 years better correlated with the increased Comfort scale than heart rate and arterial bloodpressure (3).
In the treatment of neonates there is always a discussion whether the pain behaviour scale is also valid for the most youngest group, the neonates between 22- 27 weeks gestation. These neonates react different on pain response because of their prematurity. The use of the SCA can help in this interpretation as Munster et al (2012) showed that the SCA is able to differentiate pain and discomfort in neonates between 22 - 28 weeks gestational age (4). Only Valkenburg et al (2012) showed influence of temperature regulation on the SCA outcome in a small study with 11 postoperative newborns with a low Comfortneo scale (assumed to have no pain) . The SCA was measured for 60 minutes.
All the other studies were based on short painful moments as heellance and endotracheal suctioning which are assumed to be painful.
In our NICU the Comfortneo scale is used as a standard for 3 times a day, or more when necessary. Despite these 3 measure moments we don't have exact information about the painmoments during the day. At this moment pain treatment depends on the subjective interpretation and the Comfortneo scale outcome.
Although pain is often related on painful treatments, it is not clear how long a pain sensation will last. A continuously measurement should give important information about the painful moments but also about the standard care as example the ventilated newborns or newborns on Nasale Continously Positive Airway Pressure (NCPAP). Ventilated newborns never receive pain medication automatically, as used in adults. Bellu et al (2008) described the possible adverse effects on the neurodevelopment outcome when using standard opioids in ventilated newborns. He advised to use opioids only when there is a clear pain response. Also NCPAP can be assumed to be a stressful or painful treatment because of the tight connection on the head and nose, especially in active newborns.

Study objective

A:To get insight whether respiratory support in the neonatal population, as artificially ventilation and Nasal Continously Positive Airway Pressure, will give an increased stress or pain respons which only can be detected by a 24 hours SCA meassurement, compared to the standard three times a day meassuremnt of de Comfortneo scale.

B:To compare the painscore measured by the SCA with te pain score measured by

the Comfortneo scale during standard three times measurment.

Study design

In a 2 months pilot observational cohort study, the painrespons in newborns with respiratory support (artificially ventilation or NCPAP) will be monitored by the SCA during 24 hours.The SCA pain response will be measured and scored continuously. The Comfortneo scale will be taken conform protocol: 3 times a day. The correlation between those 2 instruments will be compared at the moments of the Comfortneo scale measurement.

Intervention

Fixating the skinelectrode on the palmar and plantarlocation during 24 hours. Measuring emotional palmar and plantar sweating.

Study burden and risks

We expect that fixation of the skin electrode will not give adverse effects on parent-child contact in this stage.
The burden is expected to be low. The skin electrode can be removed without causing any skin lesions.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Gestationale age 26-42 weeks
- Postnatale age between 24-72 hours
- Artificial ventilation or NCPAP from 4 hours post partum en the exptective duration for at least 24 hours.

Exclusion criteria

-Newborns with changes in respiratory support after birth until the end of the observation period.
-Newborns with palmar or plantar skin injuries
-Newborns with recent (within 5 days) surgery.
-Newborns with congenital anomaly

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-01-2014

Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	04-07-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL40833.091.12