SKIN CONDUCTANCE, A WAY TO IMPROVE PAIN ASSESSMENT IN PREVERBAL CHILDREN?

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Primary: Is Skin Conductance a valid and reliable pain assessment tool for postoperative and procedural pain in neonates and infants < 3 yr? Secondary: 1. The effects of skin temperature, heart rate, respiration rate, blood pressure (dependent...

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

Summary

ID

NL-OMON32603

Source
ToetsingOnline

Brief title
Skin conductance in preverbal children

Condition

- Other condition

Synonym
pain

Health condition

pijn

Research involving
Human

Sponsors and support

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

Intervention

Keyword: comfort, infants, pain measurement, skin conductance

Outcome measures

Primary outcome

Skin conductance values, COMFORT behaviour scale

Secondary outcome

Parameters that may influence skin conductance

- Skin temperature

- Respiratory rate

- Oxygen saturation

- Heart rate

- Bloodpressure (Systolic, diastolic, mean)

Study description

Background summary

The goal of our study is to compare pain assessment with the validated COMFORT behavior scale with skin conductance measurements. We will perform this study in preverbal children (<3 years old) at the intensive care unit or high care unit of the Sophia Children*s Hospital. This group of patients will benefit from a more objective way of pain assessment in postoperative care and procedural pain. This study will be part of the validation process of skin conductance as a pain assessment tool.

Study objective

Primary: Is Skin Conductance a valid and reliable pain assessment tool for

postoperative and procedural pain in neonates and infants < 3 yr?

Secondary:
1. The effects of skin temperature, heart rate, respiration rate, blood pressure (dependent variables) on Skin Conductance values (primary outcome).
2. Sensitivity to change: Do Skin Conductance values significantly change after analgesic treatment?
3. Sensitivity to change: Are Skin Conductance values significantly different during a painful intervention versus a non-painful intervention?

Study design

A single centre, prospective, cross-sectional observational study

Study burden and risks

Risks to and burden for the patient are negligible. It is a non-intervention study, so there will be no benefits for the patient by participating in the study. The COMFORT behavior score is part of the standard care for children in ErasmusMC - Sophia Children*s hospital. The validation of Skin Conductance as a pain assessment tool can not be conducted without participation of the patients in our study population.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

-Written informed consent of the parents
-Children under the age of three years
-(Planned) postoperative admission to the pediatric intensive care unit / high care.

Exclusion criteria

-Withdrawal of informed consent of the parents
-Skin conditions that may affect the skin conductance at the measurement site.
-Implanted pacemaker of implanted cardioverter defibrillator.
-Local or regional anesthesia, affecting the innervation of the measurement site.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2009
Enrollment:	70

Type:	Actual

Ethics review

Approved WMO Date:	03-12-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL24509.078.08