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

Published: 03-12-2008 Last updated: 06-05-2024

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

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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**

#### **Public**

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#### Scientific

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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:	Actua

# **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