Objective measurement of behavioural parameters of pain in infants

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To test the feasibility and added value of facial electromyography to continuous pain monitoring in infants

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

Summary

ID

NL-OMON29904

Source
ToetsingOnline

Brief title
Objective measurement of behavioural parameters of pain in infants

Condition

- Other condition

Synonym
discomfort, pain

Health condition

pijn 1) tijdens vaccinatie en 2) na chirurgische ingrepen

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: behaviour, infants, muscle activity, pain

Outcome measures

Primary outcome

The primary outcome measures are the muscle activity of the corrugator supercilii and the orbicularis oculii, either during a painful event or during prolonged pain in infants at the NICU.

Secondary outcome

During the 1st part of the study only the Neonatal Facial Coding System.

During the 2nd part of the study the Neonatal Facial Coding System and the movement of the extremities and heart rate.

Study description

Background summary

Pain in infants in clinical care is an undesirable emotion. The treatment of pain is becoming an important part of the total treatment protocol. Recognition of pain in infants is complicate because infants are not able to express pain by speaking. Currently used pain assessments scales in infants are not feasible for prolonged measurements in clinical care. Additionally, the used methods are subjective. An objective and continuous pain assessment instrument is necessary to optimise the treatment of pain. One of the major parameters in current pain assessment tools is facial expression. Facial expression could be objectively measured by facial muscle activity. Results of facial muscle activity measurements are scarce and it is not yet clear whether it is possible to measure facial muscular activity on neonates. Therefore facial muscle activity will be the main outcome parameter in this study.

Study objective

To test the feasibility and added value of facial electromyography to continuous pain monitoring in infants

Study design

Cross-sectional observation study

Study burden and risks

The burden and risks associated with participation are minimal. The subjects do not undergo physical examinations or other tests; miniature sensors attached on the skin with infant-friendly tape register only natural behaviours. Since the objective of the study is pain monitoring in neonates, this study can only be done using infants because pain expressions of adults or children who can speak are not comparable to the expressions of infants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

1st part of the study:
- the neonate/baby has a gestational age of at least 36 weeks.
2nd part of the study:
- Neonates and infants aged 0-18 months
- Weight > 1500 grams
- Abdominal, including urological, or thoracic surgery

Exclusion criteria

1st part of study:
- exclusion criteria for a vaccination will be followed.
2nd part of the study:
- Receiving sedative drugs or muscle relaxants < 12 hours prior to surgery
- Receiving sedative drugs or muscle relaxants after surgery
- Neurological damage (posthypoxic encephalopathy or major congenital anomalies of the central nervous system)
- (Severe) spasticity
- Hypotonia
- Corrected gestational age < 36 weeks

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):	15-12-2006
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO Date:	06-11-2006
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	NL13073.078.06