Long-term effects of routine morphine infusion in newborns who received ventilatory support

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To evaluate detection thresholds, functioning of the HPA-axis and risk of chronic pain in children of 5-years of age who experienced pain and received morphine in neonatal period in compare with children of 5-years of age who experienced pain...

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

Summary

ID

NL-OMON29866

Source
ToetsingOnline

Brief title
Long-term effects of routine morphine and pain

Condition

- Other condition
- Neonatal and perinatal conditions

Synonym
detection thresholds, stress response

Health condition

gevoeligheid warmte/ koude, functioneren HPA-as

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: long-term, morphine, newborns, pain

Outcome measures

Primary outcome

· Detection thresholds for warmth and cold will be assessed by the thermal

sensory analyzer (TSA)

· Stress responsiveness will be assessed by collection of salivary cortisol

· Chronic pain will be assessed by The Chronic Pain Questionnaire and Pain

diary

Secondary outcome

nvt

Study description

Background summary

Worldwide, many newborns are admitted to the neonatal intensive care unit (NICU) because of prematurity, perinatal problems, congenital anomalies or severe illness. Even fairly recently, newborns on the NICU experience on average 14 painful procedures per day and more than 65% of these children does not receive appropriate analgesic therapy [1] . As several studies have indicated that neonatal pain experience might negatively affect long-term outcome [2-4], adequate analgesic therapy during neonatal intensive care is warranted (NIH/ FDA meeting April 2004).
Recently, our group showed that neonatal pain exposure results in long-term alterations in somatosensory functioning, namely hyposensitivity to the detection of temperature and hypersensitivity for pain even up to the age of 8. We also found that high dosages of morphine in children treated with ECMO resulted in generalized hyposensitivity for temperature detection. It is

possible that the amount of morphine played a role in the development of this hyposensitivity (Schouw submitted).
Neonatal pain experiences not only has effects on the somatosensory functioning, but also on the functioning of the hypothalamic-pituitary-adrenal axis (HPA-axis) [5]. It seems that pain influences stress reactions in neonates, but also has been suggested to change stress responses at older ages [6, 7]. Whether this can be prevented by the use of judicious morphine during the neonatal period is unknown.

Study objective

To evaluate detection thresholds, functioning of the HPA-axis and risk of chronic pain in children of 5-years of age who experienced pain and received morphine in neonatal period in compare with children of 5-years of age who experienced pain without morphine.

Study design

Experimental study. All children participated in this larger neonatal randomized, double-blind, placebo-controlled trial (n=150) in the Erasmus MC-Sophia Rotterdam and Isala Clinics Zwolle in the period 2000-2003 (MW-NWO-940-31-048).
All children who participated in this study will already been seen within the standard follow up for premature infants at the age of 5.3 years. As an addition this standard procedure for follow up, we will assess the detection threshold for a warm or cold stimuli and stress response.

Study burden and risks

Subjects aren*t in any risk by participating in this research. The importance of this research is to know more about the long-term effects of pain and morphine, while in future ventilated children can be better taken cared for. Previous research (P02.616C) showed that children liked to cooperate with the detection of warmt and cold, because the children control the device by themselves. Thermal limitations prevent risks of tissue dammage and pain.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Children who participated in a larger neonatal randomized, double-blind, placebo-controlled trial in the Erasmus MC-Sophia Rotterdam and Isala Clinics Zwolle in the period 2000-2003 (MW-NWO-940-31-048).

Exclusion criteria

Mental handicap

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2007
Enrollment:	192
Type:	Actual

Ethics review

Approved WMO Date:	18-09-2006
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-09-2009
Application type:	Amendment
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	NL11702.078.06