Comforting support for incubator bound children by means of maternal scent communication.

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The aim of this study is to see if we can enhance the effectiveness of the nurse*s comforting capabilities through the addition of maternal scent communication during heellance.

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

Summary

ID

NL-OMON39739

Source
ToetsingOnline

Brief title
Comforting scents

Condition

- Other condition

Synonym
pain expression, pain perception

Health condition

pijn perceptie

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Agentschap NL

Intervention

Keyword: Incubator, Parents, Premature, Scent

Outcome measures

Primary outcome

As a means of observing the baby*s perceived pain the Premature Infant Pain Profile (PIPP) will be used. The PIPP score of the first observation the will be an indication for the pain perceived by the baby.

Secondary outcome

The time it takes for the baby to reach a PIPP score of below 5 (max score of 21) will be a measurement of self regulatory capabilities of the child.
Observation intervals of the PIPP score will be 30 sec. with a maximum of total observation of 5 min.

Study description

Background summary

Since there is a need for effective non-pharmacological means of pain relieve in incubator bound neonates, various studies have been undertaken to enable parents to provide comfort to their child during their hospitalization

Study objective

The aim of this study is to see if we can enhance the effectiveness of the nurse*s comforting capabilities through the addition of maternal scent communication during heellance.

Study design

Observational, single factor, double blind, within subjects study

Study burden and risks

Data will be gathered by a trained nurse familiar with the PIPP scoring method. The nurse will be present besides the nurse who will perform a procedural heellance on the child. This means that the only burden associated with the study is the participation of an observing nurse for a total of max. 15 min. Furthermore only bare minimum risks are expected to be present for the baby, since the use of *geurdoekjes* and Kangaroo Mother Care is already widely used in the MC department.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Babies born 28> weeks GA.
- Babies with a "test age" of 32> weeks GA.
- Babies that are indicated as *safe* to include into the study by their treating nurse and/or doctor.

Exclusion criteria

- Medically unstable children or are in any threat of complications.
- Babies who are on full respiration support
- Older than 37 weeks GA

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-06-2013
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	29-01-2013

Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL42809.015.12