Amphia premature infants painstudy

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In this study, we want to find out whether breastfeeding, expressed breastmilk or sucrose gives better analgesia during a heelstick by premature neonates.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON32904

Source
ToetsingOnline

Brief title
APIP

Condition

- Other condition

Synonym
pain and discomfort

Health condition

pijn

Research involving
Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis
Source(s) of monetary or material Support: research fonds dat de vakgroep kindergeneeskunde in de afgelopen jaren samen met het ziekenhuis heeft opgebouwd

Intervention

Keyword: breasfeeding, heelstick, neonate, pain, sucrose

Outcome measures

Primary outcome

PIPP en COMFORTneo pijnscores

Secondary outcome

Not applicable.

Study description

Background summary

Only thirty years ago, it was believed that newborns couldn*t feel pain. There was also a fear for adverse events of treatment with analgesics. Because of these two reasons, newborns weren*t properly treated for their pain. Now we know that neonates do feel pain and many research has been performed concerning the measurement and treatment of pain by newborns.

Study objective

In this study, we want to find out whether breastfeeding, expressed breastmilk or sucrose gives better analgesia during a heelstick by premature neonates.

Study design

We perform an open-label, randomized controlled trial in Amphia*s hospital in Breda. Premature neonates were randomly assigned in three groups. Each group offered another way of analgesic therapy during the heelstick. Group 1 received breastfeeding during the procedure. Group 2 was given a bottle with expressed breastmilk by a nurse. And the third group received sucrose two minutes before the heelstick, lying in a cot.

Intervention

Breastfed neonates are included in the study when they are born between 32 and 37 weeks gestational age. And when there is a need for a heelstick 24 hours after birth, in a clinical setting.

The heelstick will be performed with an standardized Infant Heelstick Device. During the heelstick, newborns of the first group receive breastfeeding. Those of the second group are given expressed breastmilk by a nurse. And the third group will be treated with sucrose, lying in a cot. During the procedure, the investigator will score two pain measurement scales: the PIPP and the COMFORTneo. The procedure will be recorded and two independent persons will score the PIPP and the COMFORTneo as well.

Study burden and risks

Newborns will be observed during a heelstick, which is performed for diagnostic or screening purposes. Therefore, participation to the study doesnot effect the number of painful procedures. Since the study exists primarely of an observation, the burden for the participants is negleciable and no adverse reactions are expected by participation to the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

necessity for heelstick in breastfed newborn infant during admittance on the neonatal ward

Exclusion criteria

gestational age below 32 weeks and above 36 +6 weeks
asphyxia
sedative medication in infant or mother
drug abuse by mother

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-01-2010
Enrollment:	165
Type:	Actual

Ethics review

Approved WMO

Date:	31-12-2009

Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (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	NL30111.101.09