Magnetic non-Invasive acupuncture for Infant comfort during retinopathy of prematurity examination

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To investigate whether non-invasive ear magnetic acupuncture will help reduce pain and stress for preterm infants in the Neonatal Intensive Care Unit (NICU) during their routine eye examination for Retinopathy of Prematurity (ROP).

Ethical review	Approved WMO
Status	Will not start
Health condition type	Neonatal and perinatal conditions
Study type	Interventional

Summary

ID

NL-OMON48477

Source
ToetsingOnline

Brief title
The MAGNIFIC-ROP study

Condition

- Neonatal and perinatal conditions

Synonym
retinal disturbance due to preterm birth, retinopathy of prematurity

Research involving
Human

Sponsors and support

Primary sponsor: Neonatologie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Acupuncture, Neonate, ROP

Outcome measures

Primary outcome

Primary outcome:

- PiPP score during ROP-examination.

Secondary outcome

Secondary outcomes:

- Heart rate, arterial oxygen saturation, and respiratory rate during

ROP-examination.

Study description

Background summary

Retinopathy of Prematurity (ROP) is abnormal blood vessel development in the retina. It occurs in preterm infants (especially those born <30 weeks gestational age) because the blood vessels in the eye may stop growing and become leaky or proliferate from excess oxygen. If undetected and untreated, ROP can lead to scarring, retinal detachment and blindness. As prevention preterm infants have their eyes checked for ROP when they reach about 32-34 weeks. When there are signs of starting ROP, then treatment can be started to prevent progression of ROP.
These ROP examinations are uncomfortable and cause significant stress and pain for the preterm infants. Despite this, they are usually done without pain relief and may be repeated for several weeks. Pain relief for ROP examinations is not usual practice. Sucrose as general pain reliëf for newborn infants has been proven to be ineffectieve during this ROP examination. The only medications that are strong enough to treat the discomfort from ROP examination (opioids) may cause serious side effects (e.g. the infant stops breathing).
Both pain and pain medications in the newborn period increase the risk of poor neurodevelopmental outcomes. Finding a solution to the pain they experience is therefore one of the most important tasks we have.
Acupuncture is a form of traditional Chinese therapy that has been used for thousands of years to prevent and treat pain and other health problems. It can

be applied in multiple ways including the traditional needles, by laser, by pressure or by magnets.
In a pilot study, it has been shown that non-invasive ear acupuncture, (i.e. acupuncture without needles) using magnets on 5 ear acupuncture points in newborn infants, is able to reduce pain during a heel prick for blood tests. Therefore we would like to investigate whether this non-invasive ear magnetic acupuncture can reduce pain and stress during ROP examination in preterm infants.

Study objective

To investigate whether non-invasive ear magnetic acupuncture will help reduce pain and stress for preterm infants in the Neonatal Intensive Care Unit (NICU) during their routine eye examination for Retinopathy of Prematurity (ROP).

Study design

Study Design: Randomized control trial
Number of centres: Multi-centre (Edmonton, Canada; Sydney, Australia, Nijmegen, Netherlands)

Intervention

Intervention:
Included infants will be randomized to one of the following study arms:
1. Intervention group: Infants will have non-invasive ear magnetic acupuncture during a ROP-exam.
Four ear magnets will be placed on each ear of the infant at 1 hours before the ROP-examination by a neonatologist-acupuncturist. The magnets will be placed on the baby*s ear and removed after the ROP-examination. The magnets will be replaced if they are displaced before the ROP-exam and removed if there are complications (e.g. skin reactions, not previously documented on other patients). The magnets stick to skin with a zelf-adhesive sticker (skin reactions have not been reported). They are also inert so will be passed out in stools if ingested.
2. Control group: Infants will have placebo during a ROP-exam.
Four placebo stickers will be placed on each ear of the infant at 1 hours before the ROP-examination by a neonatologist-acupuncturist. The placebo stickers will be placed on the baby*s ear and removed after the ROP-exam. The placebo stickers will be replaced if they are displaced before the ROP-exam and removed if there are complications (e.g. skin reactions, not previously documented on other patients). The placebo zelf-adhesive stickers will be attached to skin (skin reactions have not been reported). They are also inert so will be passed out in stools if ingested.

Blinding

Nursing staff (pain assessors) will be blinded to the arm that the baby is randomized to. Only the neonatologist-acupuncturist applying the stickers will be aware of the allocation the infant has received. The flesh coloured stickers will conceal the presence of the magnets. Stickers will be replaced if they fall off and data will continue to be recorded.

Assessment of pain/stress response:
1. Infant vital signs (heart rate/ arterial oxygen saturation / respiratory rate) before, during and after the procedure will be recorded using the bedside monitor of the infant
2. The Preterm Infant Pain Profile (PIPP) score before, during after the procedure will be assessed by the bedside nurse.
3. Pain management will be as per NICU policy. All infants will receive sucrose prior eye-exam. Further pain management is limited to supportive care (e.g. swaddling and cuddling, feeding). Data will be collected on pain management strategies.
4. Event recording: The bedside nurse will record: time and duration of pain/stress events on a separate data sheet for correlation with vital sign changes

In addition, common neonatal data including respiratory support at the neonatal unit, incidence of patent ductus arteriosus, intraventricular hemorrhage, periventricular leukomalacia, necrotizing enterocolitis, oxygen/respiratory support at 36 weeks postmenstrual age, neonatal death <28 days, death before discharge, days on ventilator, age of discontinuation of respiratory support, age at discharge home, length of during hospital stay, will be recorded from electronic patient file in order to compare whether both study groups have the same background characteristics.

Study burden and risks

Risks
- Stickers:
There are no anticipated risks. The stickers may fall off and need to be replaced. Skin reactions from the adhesive have not been reported.
- Magnets
Although previously not reported, there is a theoretical risk that the infant can swallow the magnet. In such cases, the parent will be informed and a chest and abdominal X-Ray taken to verify where the magnet is. The magnet is inert and will pass out in the stools in due time.

Benefit
Preterm infants will require ROP-examination to assess development and severity of ROP. This is accompanied by pain and stress. Pain increases the risk of adverse neurodevelopmental outcome in later life but unfortunately, so do many of the medications that are used to prevent or treat pain. If non-invasive magnetic ear acupuncture can be shown to both reduce pain perception and

improve infant comfort, we will be able to reduce the need for potentially toxic medications and improve long-term neurological outcomes for hundreds of preterm infants every year.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Infants <29 weeks and <1250g birth weight who require ROP-examination

Exclusion criteria

1. No consent
2. Chronic pain stimuli (e.g. invasive mechanical ventilation)

3. Neurological problems that could impair pain perception (e.g. severe brain injury)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO Date:	29-07-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL68700.091.19