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Reducing pain intensity in neonates by multisensory stimulation

Submission date
10/01/2019

Recruitment status
No longer recruiting

Registration date
24/01/2019

Overall study status
Completed

Last Edited
13/01/2021

Condition category
Neonatal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
During treatment in the neonatal ward, infants receive medical and non-medical care that can cause pain. Prevention and treatment of pain in newborns is very important, but in fact, of the many procedures that cause pain, management of pain carried out by health workers is still very limited. The use of glucose or sucrose (sugar) is more effective for pain relief when it is combined with other sensory stimulus (five senses), known as sensorial saturation (SS). SS includes stimulation of five senses: gustatory (taste), visual (sight), tactile (touch), auditory (sound) and olfactory (smell). It is performed by giving a sweet taste, looking at baby's face, massaging gently, talking quietly, and giving perfume to the nurse's hand. In this study glucose /sucrose is replaced with breast milk because it is safe and provides a calming effect from its aroma for a long period, making it useable as smell stimulation. The aim of this study is to compare the effects of different multisensory methods using sucrose and breast milk on babies' pain when undergoing blood sampling.

Who can participate?
2 to 28 day old babies admitted to the neonatal ward and undergoing peripheral blood sampling procedure

What does the study involve?
The babies are randomly allocated into three groups to receive multisensory stimulation with sucrose, multisensory stimulation with breast milk, or sucrose without multisensory stimulation, and their pain is measured when undergoing the blood sampling procedure.

What are the possible benefits and risks of participating?
The benefit of participating is the baby undergoing blood sampling can get treatment for relieving pain. No risks are expected as the treatment is standard procedure in some hospitals.

Where is the study run from?
Two general hospitals in West Java province in Indonesia

When is the study starting and how long is it expected to run for?
January 2017 to December 2018

Who is funding the study?
Ministry of Research, Technology and Higher Education (Indonesia)

Who is the main contact?
Mrs Siti Yuyun Rahayu Fitri

Contact information

Type(s)
Scientific

Contact name
Mrs Siti Yuyun Rahayu Fitri

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Multisensory stimulation as an effort to reduce pain Intensity in neonates

Study objectives
1. Analgesia methods of multisensory stimulation using breast milk is no different to multisensory stimulation using sucrose in regard to its effect on pain intensity in neonates
2. Multisensory stimulation using breast milk is better than using sucrose as an analgesia method
3. Analgesia method of multisensory stimulation using sucrose is better than analgesia method using only sucrose regarding pain intensity in neonates

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical and health research ethics committee (MHREC) Faculty of Medicine Universitas Gadjah Mada Yogyakarta Indonesia, Gedung Radiopoetro Lt 2 Sayap Barat, Jl. Farmako, Sekip Utara, Yogyakarta, Indonesia 55128, Tel: 0274 588688 pswt 17225 , +62811-2666-869, Email: mhrec_fmugm@ugm.ac.id, No. KE/FK/1193/EC/2017

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
2 to 28 days old babies admitted to neonatal ward who underwent peripheral blood sampling procedure

Interventions
Randomisation with a block randomisation method to 3 interventions:

Multisensory stimulation (modification of sensorial saturation/SS):

1. SS analgesia methods of modified breast milk (test group):
- Prepare 1 cc syringe and 1 cc of breast milk
- Start talking to the baby 30 seconds before blood sample collection
- Gently massage baby's face
- Bring the breast milk closer to baby's nose
- Give breast milk until the baby sucks rhythmically
- Perform blood sample collection while doing those maneuvers
- Continue gentle massage and speak to the baby until the end of the procedure
- Measure pain intensity using PIPP-R instrument

2. Standard SS analgesia method (reference group):
- Prepare a vial of sucrose 24 %
- Start talking to the baby 30 seconds before blood sample collection
- Gently massage the baby's face
- Give sucrose 24 % until he/she sucks rhythmically
- Perform blood sample collection while doing those maneuvers
- Continue gentle massage and talking to the baby until the end of the procedure
- Measure pain intensity using PIPP-R instrument

3. Sucrose 24% analgesia method (control group):
- Prepare the baby for blood sample collection
- Prepare a vial of sucrose 24%
- Give sucrose 24 % until he/she sucks rhythmically
- Perform blood sample collection while doing those maneuvers
- Measure pain intensity using PIPP-R instrument

Intervention Type
Other

Primary outcome measure
Pain intensity measured using PIPP-R (Premature Infant Pain Profile-Revised) at a single timepoint

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/01/2017

Completion date
30/12/2018

Eligibility

Key inclusion criteria
1. Baby undergoing peripheral blood sampling procedure
2. Minimum APGAR Score of 9 at 5 minutes
3. Gestational age > 32 weeks
4. Postnatal age of 48 hours
5. Sucking and swallowing reflex (+)
6. On treatment for less than 7 days
7. Received breast milk from mother

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
108

Total final enrolment
108

Key exclusion criteria

Neonates who were given analgesic and sedative drug

Date of first enrolment
12/04/2018

Date of final enrolment
03/08/2018

Locations

Countries of recruitment
Indonesia

Study participating centre
Universitas Gadjah Mada
Doctoral program faculty of medicine, public health and nursing
Jl. Farmako, Senolowo, Sekip Utara, Sleman
Yogyakarta
Indonesia
55281

Sponsor information

Organisation
Universitas Gadjah Mada

Sponsor details
Faculty of medicine, public health and nursing
Jl. Farmako, Senolowo Sekip Utara
Yogyakarta
Indonesia
55281

Sponsor type
University/education

ROR
https://ror.org/03ke6d638

Funder(s)

Funder type
Government

Funder Name
Kementerian Riset Teknologi Dan Pendidikan Tinggi Republik Indonesia

Alternative Name(s)
Ministry of Research, Technology and Higher Education, Kementerian Ristek Dikti, Kementerian Riset dan Teknologi

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Indonesia

Results and Publications

Publication and dissemination plan
Planned publication in BMC Nursing

Intention to publish date
01/03/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Siti Yuyun Rahayu Fitri

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2020	13/01/2021	Yes	No