Reducing pain intensity in neonates by multisensory stimulation

Submission date	Recruitment status No longer recruiting	Prospectively registered		
10/01/2019		Protocol		
Registration date	Overall study status	Statistical analysis plan		
24/01/2019	Completed	[X] Results		
Last Edited 13/01/2021	Condition category Neonatal Diseases	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

ORCID ID

https://orcid.org/0000-0002-4816-9935

Contact details

Jl Tulip III No 8 Bumi Rancaekek Kencana, Rancaekek Bandung Indonesia 40394

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

There are no secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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

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

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