

# Reducing pain intensity in neonates by multisensory stimulation

<b>Submission date</b> 10/01/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 24/01/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/01/2021	<b>Condition category</b> Neonatal Diseases	<input type="checkbox"/> 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  
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Indonesia  
40394

## Additional identifiers

## 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?
<a href="#">Results article</a>	results	01/07/2020	13/01/2021	Yes	No