# The efficacy of mother's involvement to comfort infants during immunization

| Submission date               | Recruitment status No longer recruiting | Prospectively registered       |  |  |
|-------------------------------|---|--------------------------------|--|--|
| 17/08/2019                    |   | Protocol                       |  |  |
| Registration date             | Overall study status Completed          | Statistical analysis plan      |  |  |
| 21/08/2019                    |   | [X] Results                    |  |  |
| <b>Last Edited</b> 11/03/2020 | Condition category Neonatal Diseases    | [] Individual participant data |  |  |
| 1 1/03/2020                   | ואכטוומנמו טומכממכמ                     |                                |  |  |

### Plain English summary of protocol

Background and study aims

A diphtheria pertussis tetanus (DPT) immunization often causes trauma in infants because it's done by intramuscular injection.

The aim of this study is to determine the effect of facilitated tucking by mothers combined with sitting up position on the level of pain when infants received DPT immunization

### Who can participate?

Infants aged 2-12 months that underwent DPT immunization in Bangetayu Health Center Semaran and their mothers

### What does the study involve?

Participants will be randomly allocated to one of three groups: (A) facilitated tucking (making flexion on the infant arm) by mothers (B) facilitated tucking by a health worker (C) sitting up position

What are the possible benefits and risks of participating? Benefit: alleviate the pain level in infants, make the infants more comfort Risk: there is no risk in this study

Where is the study run from? Bangetayu Health Center, Indonesia

When is the study starting and how long is it expected to run for? August 2018 for one month

Who is funding the study? Sultan Agung Islamic University

Who is the main contact? Nopi Nur Khasanah nopi.khasanah@unissula.ac.id

# Contact information

### Type(s)

Public

#### Contact name

Mrs Nopi Khasanah

#### Contact details

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# Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

207/A.1/FIK-SA/VII/2018

# Study information

#### Scientific Title

Facilitated tucking by mothers compared to facilitated tucking by health worker, facilitated tucking by mothers compared to sitting up position by mothers, facilitated tucking by health worker compared to sitting up position by mothers in the comfort of infants during the intramuscular immunization procedure

## **Study objectives**

Facilitated tucking is more effective done by mothers then by health worker

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 13/07/2018 Ethics Committee of the Faculty of Nursing, Unissula (Komite Etik Fakultas Ilmu Keperawatan Unissula, Jl. Raya Kaligawe Km. 4 Semarang 50112, Po Box 1054, Indonesia; +62 24 6583584), ref: 207/A.1/FIK-SA/VII/2018

### Study design

Interventional randomised controlled trial

### Primary study design

Interventional

### Study type(s)

Prevention

### Health condition(s) or problem(s) studied

Infant distress during immunization procedure

#### **Interventions**

Participants are divided into three groups randomly by picking up one of three folded paper (A/B /C, A means that the participants included in group 1; B means that participants included in group 2; C means participants included in the control group).

After random allocation, all participants fill out the questionnaire and for the mothers and the health worker wearing the same clothes as the mother.

Group 1: infants sitting up on the mother's lap and mothers make infant's arm flex then the midwife will give an intramuscular immunization

Group 2: infants sitting up on the health worker lap and health worker make infant's arm flex then the midwife will give an intramuscular immunization

Control group: infants sitting up on the mother's lap then the midwife will give an intramuscular immunization.

Video recorded on each participant roughly 5 minutes and send to a pediatric nurse specialist to observe and rate pain according to the FLACC scale.

Data were analyzed by Kruskal-Wallis test and post hoc Mann-Whitney test.

### Intervention Type

Procedure/Surgery

## Primary outcome(s)

Pain level in infants measured using FLACC (face, legs, activity, cry, consolability) scale at the time of immunisation

## Key secondary outcome(s))

Infants age

## Completion date

19/09/2018

# **Eligibility**

# Key inclusion criteria

Infants aged 2-12 months that underwent DPT immunization in Bangetayu Health Center Semarang

# Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Neonate

### Sex

All

### Total final enrolment

48

### Key exclusion criteria

Infants with chronic condition

### Date of first enrolment

08/08/2018

### Date of final enrolment

29/08/2018

# Locations

### Countries of recruitment

Indonesia

### Study participating centre Bangetayu Health Center

JL. Bangetayu Genuk Semarang Indonesia 50115

# Sponsor information

### Organisation

Sultan Agung Islamic University

#### **ROR**

https://ror.org/015hejj83

# Funder(s)

# Funder type

University/education

### Funder Name

Universitas Islam Sultan Agung

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Available on request

# **Study outputs**

| Output type                   | Details                       | Date created | Date added | Peer reviewed? | Patient-facing? |
|-------------------------------|-------------------------------|--------------|------------|----------------|-----------------|
| Results article               | results                       | 01/12/2019   | 11/03/2020 | Yes            | No              |
| Participant information sheet | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |