

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

Submission date 17/08/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/08/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/03/2020	Condition category Neonatal Diseases	<input type="checkbox"/> Individual participant data

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 Semarang 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

Jl Raya Kaligawe Km.4

Semarang

Indonesia

50112

+6285640256378

nopi.khasanah@unissula.ac.id

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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

Secondary outcome measures

Infants age

Overall study start date

13/07/2018

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

Age group

Neonate

Sex

Both

Target number of participants

48

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

Sponsor details

Jl Raya Kaligawe km.4

Semarang

Indonesia

50112

(024) 6583584

info@unissula.ac.id

Sponsor type

University/education

Website

<http://www.unissula.ac.id>

ROR

<https://ror.org/015hejj83>

Funder(s)

Funder type

University/education

Funder Name

Universitas Islam Sultan Agung

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

The datasets generated during and/or analysed during the current study are/will be available upon request from <https://drive.google.com/drive/folders/1QhTTRvVMhkhVXdCzofiPPuWrpyMCc5uE?usp=sharing> (Name: Nopi Nur Khasanah, Email: nopi.khasanah@unissula.ac.id, type of data: video recorded, The data will become available on August 2019 for 2 years, data will be shared by google drive, types of analyses by observational, and the mechanism by FLACC scale, consent from participants was obtained, data was anonymous, no legal restrictions)

Intention to publish date

18/09/2019

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