

TCTR ID : TCTR20180306002

Overall Recruitment Status : Completed (Has Results)

OTHER ID :

Prospective registration
This protocol was registered before enrollment of the first participant.

Tracking Information

First Submitted Date : 06 March 2018

First Posted Date : 06 March 2018

Last Update Posted Date : 05 October 2024

Title

Public Title : Effect of oropharyngeal milk administration on the oral and gut microbiota of very low birth weight infant: Randomized controlled trial

Acronym : OralGutMicrobiota

Scientific Title : Effect of oropharyngeal milk administration on the oral and gut microbiota of very low birth weight infant: Randomized controlled trial

Sponsor ID/ IRB ID/ EC ID : 60-455-01-1

Registration Site : Thai Clinical Trials Registry

URL : <https://www.thaiclinicaltrials.org/show/TCTR20180306002>

Secondary ID : No Secondary ID

Ethics Review

1. Board Approval : Submitted, approved

Approval Number : 60-455-01-1

Date of Approval : No Data

Board Name : the Ethics Committee of the Faculty of Medicine, Prince of Songkla University

Board Affiliation : Prince of Songkla University

Board Contact : Business Phone : 074451157 Ext. No Data

Business Email : medpsu.ec@gmail.com

Business Address : Office of Human Research Ethics Committee 15 Karnjanavanit Road, Hat Yai, Songkhla 90110, Thailand

Sponsor

Source(s) of Monetary or Material Supports : Targeted Research Grants, Faculty of Medicine, Prince of Songkla University

Study Primary Sponsor : Targeted Research Grants, Faculty of Medicine, Prince of Songkla University

Responsible Party : Name/Official Title : Office of Human Research Ethics Committee

Organization : Faculty of Medicine, Prince of Songkla University

Phone : 074451157 Ext. No Data

Email : medpsu.ec@gmail.com

Study Secondary Sponsor : Faculty of Medicine, Prince of Songkla University

Protocol Synopsis

Protocol Synopsis : Very low birthweight (VLBW) infants challenge the pediatricians to reduce the mortality and major complications. Colostrum and breastmilk strongly benefit in those neonates. Oral immune therapy (OIT) or oropharyngeal milk may be an advantage to build oral and gut microbiota and higher the level of immune-protective factors during oral feeding by themselves. However, there are a few RCT of OIT compared with control in VLBW infants. We will intervene a RCT by giving between OIT and sterile water groups in VLBW infants to compare oral or gut microbiota and clinical outcomes. Moreover, we will compare between oral or gut microbiota and clinical outcomes.

URL not available

Health Conditions

Health Condition(s) or Problem(s) Studied : Preterm infant Oral care Microbiota

Keywords : Gastrointestinal Microbiome Microbiota Oral immune therapy Oropharyngeal milk Very low birth weight infant

Eligibility

Inclusion Criteria :
1 Very low birth weight neonate (birth weight less than 1,500 grams)
2 Inborn neonate

Gender : Both

Age Limit : Minimum : 1 Days Maximum : 28 Days

Exclusion Criteria :
1 Maternal death
2 Contraindication of breast milk eg maternal HIV infection
3 Gut anomalies
4 Chromosome abnormality or moribund

Accept Healthy Volunteers : No

Status

Overall Recruitment Status : Completed

Key Trial Dates	Study Start Date (First enrollment) : 01 July 2018	Indicate Type : Actual
	Completion Date (Last subject, Last visit) : 30 June 2020	Indicate Type : Actual
	Study Completion Date : 31 December 2020	Indicate Type : Actual

Design

Study Type : Interventional

Primary Purpose : Basic Science

Study Phase : Phase 0

Intervention Model : Parallel

Number of Arms : 2

Masking : Open Label

Allocation : Randomized

Control : No treatment / Standard of care

Study Endpoint Classification : Efficacy Study

Sample size

Planned sample size : 100

Actual sample size at study completion : 63

Intervention Arm 1

Intervention name : Oropharyngeal milk

Intervention Type : Experimental

Intervention Classification : Dietary Supplement

Intervention Description : Nurses will give 0.1 mL of breast milk into each buccal pouch every 3 hours until 28th date of postnatal age or the neonate will be oral fed (breastfeed or bottom feed) by themselves, whichever comes first.

Intervention Arm 2

Intervention name : Sterile water

Intervention Type : Placebo Comparator

Intervention Classification : Other

Intervention Description : Nurses will give 0.1 mL of sterile water into each buccal pouch every 3 hours until 28th date of postnatal age or the neonate will be oral fed (breastfeed or bottom feed) by themselves, whichever comes first.

Outcome**Primary Outcome**

1. Outcome Name : Oral and gut microbiota

Metric / Method of measurement : NextGen

Time point : Oral feed (oral) or 28 days of life (gut)

Secondary Outcome

1. Outcome Name : Clinical outcomes

Metric / Method of measurement : record form
 Time point : until death or discharge

Location

Section A : Central Contact

Central Contact	First Name : Anucha Degree : M.D.	Middle Name : Phone : 075451257 Ext. : No Data	Last Name : Thatrimontrichai Email : tanucha@medicine.psu.ac.th
Central Contact Backup	First Name : Jenjira Degree : B.S	Middle Name : Phone : 075451276 Ext. : No Data	Lastname : Seachan Email : jenjira.s@outlook.com

Section B Facility Information and Contact

- Site Name : Department of Pediatrics, Prince of Songkla University
 City : Hat Yai
 Country : Thailand
- Recruitment Status : Active, not recruiting
- Facility Contact** First Name : Anucha
Degree : M.D.
- Facility Contact Backup** First Name : Jenjira
Degree : B.S
- Investigator Name** First Name : Anucha
Degree : M.D.

Middle Name : Phone : 075451257 Ext. : No Data	Last Name : Thatrimontrichai Email : tanucha@medicine.psu.ac.th
Middle Name : Phone : 075451276 Ext. : No Data	Last Name : Seachan Email : jenjira.s@outlook.com
Middle Name : Role : Principal Investigator	Last Name : Thatrimontrichai

Section C : Contact for Public Queries (Responsible Person)

First Name : Anucha Degree : M.D.	Middle Name : Phone : 075451257 Ext. : No Data	Last Name : Thatrimontrichai Email : tanucha@medicine.psu.ac.th
Postal Address : Department of Pediatrics, Prince of Songkla University State/Province : Songkhla	Postal Code : 90110	
Country : Thailand	Official Role : Study Principal Investigator	
Organization Affiliation : Prince of Songkla University		

Section D : Contact for Scientific Queries (Responsible Person)

First Name : Anucha Degree : M.D.	Middle Name : Phone : 075451257 Ext. : No Data	Last Name : Thatrimontrichai Email : tanucha@medicine.psu.ac.th
Postal Address : Department of Pediatrics, Prince of Songkla University State/Province : Songkhla	Postal Code : 90110	
Country : Thailand	Official Role : Study Principal Investigator	
Organization Affiliation : Prince of Songkla University		

Summary Results

Date of posting of results summaries : 05 October 2024

Date of first journal publication of results : 01 September 2023

URL Link to Results : https://journals.lww.com/pidj/fulltext/2023/09000/long_duration_of_oral_care_using_mother_s_own_milk.16.aspx

Baseline Characteristics : The baseline characteristics did not differ between the MOM and SW groups. The median duration of oral care was slightly shorter in the MOM group than in the SW group, but the difference was not statistically significant.

Participant Flow : A total of 116 VLBW neonates were admitted to the NICU during the study period. Among these, 63 neonates were enrolled and randomized. A total of 30 and 33 neonates were allocated to the MOM and SW groups, respectively.

Adverse events : There were no significant differences in composite outcomes, mortality, severe infection (LOS, NEC, or VAP), pneumonia and sequelae from oxygen toxicity (moderate-to-severe bronchopulmonary dysplasia and retinopathy of prematurity stage 2-3) between the two groups.

Outcome Measures : The MOM group had a significantly lower risk of clinical sepsis than the SW group (47% vs. 76%).

Brief Summary of Results : A longer duration of oral care using MOM in VLBW infants sustains healthy bacteria and decreases the risk of clinical sepsis.

Deidentified Individual Participant-level Data Sharing

Plan to share IPD : No

Reason : Need a consensus from colleagues

Publication from this study

MEDLINE Identifier : 37343216

URL link to full text publication : <https://pubmed.ncbi.nlm.nih.gov/37343216/>
