TCTR ID: TCTR20180306002 OTHER ID: Overall Recruitment Status: Completed (Has Results)

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

 $Date\ of\ Approval:\ \ \operatorname{No}\ \operatorname{Data}$

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

Intervantion 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.

Intervantion 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 Middle Name : Last Name : Thatrimontrichai

Degree: M.D. Phone: 075451257 Ext.: No Data Email: tanucha@medicine.psu.ac.th

Central Contact Backup First Name: Jenjira Middle Name: Lastname: Seachan

Degree : B.S Phone : 075451276 Ext. : No Data Email : jenjira.s@outlook.com

Section B Facility Information and Contact

1. Site Name: Department of Pediatrics, Prince of Songkla University

City: Hat Yai State/Province: Songkhla Postal Code: 90110

Country: Thailand Recruitment Status: Active, not recruiting

Facility Contact First Name : Anucha Middle Name : Last Name : Thatrimontrichai

Degree: M.D. Phone: 075451257 Ext.: No Data Email: tanucha@medicine.psu.ac.th

Facility Contact Backup First Name : Jenjira Middle Name : Last Name : Seachan

 $\label{eq:decomposition} Degree: \grave{a}, {}^{\circ}\!B.S \qquad \qquad Phone: 075451276 \ Ext.: No \ Data \qquad Email: jenjira.s@outlook.com$

Investigator Name : First Name : Anucha Middle Name : Last Name : Thatrimontrichai

Degree : M.D. Role : Principal Investigator

Section C: Contact for Public Queries (Responsible Person)

First Name : Anucha Middle Name : Last Name : Thatrimontrichai

Degree: M.D. Phone: 075451257 Ext.: No Data 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 Middle Name : Last Name : Thatrimontrichai

Degree : M.D. Phone : 075451257 Ext. : No Data 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.1

6.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/