

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

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/>
