

TCTR ID : TCTR20221024003

Overall Recruitment Status : Enrolling by invitation

OTHER ID :

Retrospective registration
This protocol was registered after enrollment of the first participant.

Tracking Information

First Submitted Date : 22 October 2022
First Posted Date : 24 October 2022
Last Update Posted Date : 22 October 2022

Title

Public Title : The difference of infant's gut microbiome between cesarean delivery and vaginal delivery
Acronym : No Data
Scientific Title : The difference of infant's gut microbiome between cesarean delivery and vaginal delivery
Sponsor ID/ IRB ID/ EC ID : 2565URMS0847
Registration Site : Thai Clinical Trials Registry
URL : <https://www.thaiclinicaltrials.org/show/TCTR20221024003>
Secondary ID : No Secondary ID

Ethics Review

1. Board Approval : Submitted, approved
Approval Number : SWUEC/E/M-029/2564
Date of Approval : 05 November 2021
Board Name : Strategic Wisdom and Research Institute
Board Affiliation : Srinakharinwirot University, Thailand
Board Contact : Business Phone : 026495000 Ext. No Data
Business Email : ethics@g.swu.ac.th
Business Address : 114 Sukhumvit Rd. Kwaeng Klong Toei NUea, Khet Watthana, Bangkok, 10110

Sponsor

Source(s) of Monetary or Material Supports : Strategic Wisdom and Research Institute, Srinakharinwirot University
Study Primary Sponsor : Strategic Wisdom and Research Institute, Srinakharinwirot University
Responsible Party : Name/Official Title : Strategic Wisdom and Research Institute, Srinakharinwirot University
Organization : Srinakharinwirot University, Thailand
Phone : 026495000 Ext. No Data
Email : nongpruksa.j@gmail.com
Study Secondary Sponsor : Fundamental Fund, National Research and Innovation Information System

Protocol Synopsis

Protocol Synopsis : To study the difference of infant's gut microbiome between cesarean delivery and vaginal delivery and the factors that possibly involving in infant's gut microbiome in term healthy newborn delivered from 280 pregnant women.

URL not available

Health Conditions

Health Condition(s) or Problem(s) Studied : Infant gut microbiome
Keywords : microbiome, gut, infant, cesarean, vaginal delivery

Eligibility

Inclusion Criteria : 1. Term healthy newborn with normal vital signs and physical examination. 2. Delivered at HRH Maha Chakri Sirindhorn Medical Center, Faculty of Medicine, Srinakharinwirot University, Thailand. 3. Delivered from pregnant women with no infection history. 4. Delivered from pregnant women not received antibiotic treatment except for Cesarean empirical antibiotic prophylaxis.
Gender : Both
Age Limit : Minimum : N/A (No limit) Maximum : 48 Hours

Exclusion Criteria : 1. Infant's fecal specimen cannot be corrected within 48 hours after delivery
2. Infant diagnosed with gastrointestinal abnormalities, other structural abnormalities or genetic disease after delivery.
3. Infant diagnosed with complications after delivery e.g., jaundice that need phototherapy or exchanged transfusion, early neonatal sepsis
4. Infant received antibiotic within 48-72 hours after delivery before collecting the fecal specimen.

Accept Healthy Volunteers : Yes

Status

Overall Recruitment Status : Enrolling by invitation

Key Trial Dates Study Start Date (First enrollment) : 24 April 2021 Indicate Type : Actual

Completion Date (Last subject, Last visit) : 31 December 2022 Indicate Type : Anticipated

Study Completion Date : 31 March 2023 Indicate Type : Anticipated

Design

Study Type : Observational

Primary Purpose : Basic Science

Number of Groups : 2

Study Endpoint Classification : N/A

Sample size

Planned sample size : 280

Actual sample size at study completion :

Observation Group 1

Group name : Vaginal delivery

Group Description : Infants delivered by vaginal delivery

Observation Group 2

Group name : Cesarean delivery

Group Description : Infants delivered by cesarean delivery

Outcome

Primary Outcome

1. Outcome Name : Alpha diversity

Metric / Method of measurement : QIMME

Time point : After complete sample collection

2. Outcome Name : Difference of gut microbiomes

Metric / Method of measurement : Non-parametric t-test

Time point : After complete sample collection

Secondary Outcome

1. Outcome Name : Gravida

Metric / Method of measurement : Record form

Time point : 1 year

2. Outcome Name : Parity

Metric / Method of measurement : Record form

Time point : 1 year

3. Outcome Name : Abortion

Metric / Method of measurement : Record form

Time point : 1 year

4. Outcome Name : Gestational age

Metric / Method of measurement : Record form

Time point : 1 year

5. Outcome Name : Ethnic

Metric / Method of measurement : Record form
Time point : 1 year
6. Outcome Name : Income
Metric / Method of measurement : Record form
Time point : 1 year
7. Outcome Name : Religion
Metric / Method of measurement : Record form
Time point : 1 year
8. Outcome Name : BMI
Metric / Method of measurement : Record form
Time point : 1 year
9. Outcome Name : ANC risk
Metric / Method of measurement : Record form
Time point : 1 year
10. Outcome Name : Medications
Metric / Method of measurement : Record form
Time point : 1 years
11. Outcome Name : Underlying disease
Metric / Method of measurement : Record form
Time point : 1 year
12. Outcome Name : Route of delivery
Metric / Method of measurement : Record form
Time point : 1 year
13. Outcome Name : Intrapartum complications
Metric / Method of measurement : Record form
Time point : 1 year
14. Outcome Name : Postpartum complications
Metric / Method of measurement : Record form
Time point : 1 year
15. Outcome Name : Infant sex
Metric / Method of measurement : Record form
Time point : 1 year
16. Outcome Name : Birth body weight
Metric / Method of measurement : Record form
Time point : 1 year
17. Outcome Name : APGAR score
Metric / Method of measurement : Record form
Time point : 1 year

Location

Section A : Central Contact

Central Contact	First Name : Nichapat	Middle Name :	Last Name : Pahirah
	Degree :	Phone : 037395085 Ext. : 60811	Email : anoonp@gmail.com
Central Contact Backup	First Name : Wipada	Middle Name :	Lastname : Laosooksathit
	Degree :	Phone : 037395085 Ext. : 60811	Email : wipada@g.swu.ac.th

Section B Facility Information and Contact

1. Site Name : HRH Maha Chakri Sirindhorn Medical Center		
City : Ongkharak	State/Province : Nakornnayok	Postal Code : 26120
Country : Thailand	Recruitment Status : Recruiting	
Facility Contact	First Name : Nichapat	Middle Name :
	Degree :	Phone : 037395085 Ext. : 60811
		Last Name : Pahirah
		Email : anoonp@gmail.com

Facility Contact Backup	First Name : Wipada	Middle Name :	Last Name : Laosooksathit
	Degree :	Phone : 026495000 Ext. : No Data	Email : wipada@g.swu.ac.th
Investigator Name	First Name : Nichapat	Middle Name :	Last Name : Pahirah
	Degree :	Role : Principal Investigator	

Section C : Contact for Public Queries (Responsible Person)

First Name : Nichapat	Middle Name :	Last Name : Pahirah
Degree : No Data	Phone : 037395085 Ext. : 60811	Email : anoonp@gmail.com
Postal Address : 62 Moo 7 Ongkharak Ongkharak		
State/Province : Nakhonnayok	Postal Code : 26120	
Country : Thailand	Official Role : Study Principal Investigator	
Organization Affiliation : Faculty of Medicine, Srinakharinwirot University		

Section D : Contact for Scientific Queries (Responsible Person)

First Name : Nichapat	Middle Name :	Last Name : Pahirah
Degree : No Data	Phone : 037395085 Ext. : 60811	Email : anoonp@gmail.com
Postal Address : 62 Moo 7 Ongkharak Ongkharak		
State/Province : Nakhonnayok	Postal Code : 26120	
Country : Thailand	Official Role : Study Principal Investigator	
Organization Affiliation : Faculty of Medicine, Srinakharinwirot University		

Deidentified Individual Participant-level Data Sharing

Plan to share IPD : No
Reason : Need consensus from colleagues

Publication from this study

MEDLINE Identifier : No Data
URL link to full text publication : No Data
