TCTR ID: TCTR20190622001 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: 22 June 2019
First Posted Date: 22 June 2019
Last Update Posted Date: 27 August 2021

Title

Public Title: Vitamin D Status in Full-term Exclusive Breastfed Infants versus Full-term Breastfed Infants Receiving

Vitamin D Supplement in Thailand

Acronym: No Data

Scientific Title: Vitamin D Status in Full-term Exclusive Breastfed Infants versus Full-term Breastfed Infants Receiving

Vitamin D Supplement in Thailand

Sponsor ID/ IRB ID/ EC ID: MURA2018/860

Registration Site: Thai Clinical Trials Registry

URL: https://www.thaiclinicaltrials.org/show/TCTR20190622001

Secondary ID : Other Identifier; Issuing Organization :  $RF\_62054$ 

**Ethics Review** 

1. Board Approval: Submitted, approved

Approval Number: 10-61-58

Date of Approval: 30 November 2018

Board Name: Office of The Committee for Research, Faculty of Medicine Ramathibodi Hospital

Board Affiliation: Mahidol University

Board Contact: Business Phone: 6602012175 Ext. No Data

Business Email: raec.mahidol@gmail.com

Business Address: 270 Rama 6 Rd. Phayatai, Ratchatewi Bangkok 10400 Thailand

Sponsor

Source(s) of Monetary or Material Supports: Faculty of Medicine Ramathibodi Hospital

Study Primary Sponsor: Faculty of Medicine Ramathibodi Hospital

Responsible Party: Name/Official Title: Chayatat Ruangkit, MD

Organization: Chakri Naruebodindra Medical Institute, Faculty of Medicine Ramathibodi Hospital

Phone: 0951656605 Ext. No Data Email: chayatatr@hotmail.com

Study Secondary Sponsor: Pending

**Protocol Synopsis** 

Protocol Synopsis: In Thailand, there is no clear guideline on vitamin D supplementation for infants. Currently, there is not

enough information about vitamin D status in Thai infants to support physician decisions or to guide medical practice. The study participants will be recruited from the mother who brings the infants for a routine health check at the well-baby clinic at the age of 2-3 months. Only the mothers who have been successfully exclusively breastfed and have an intention to exclusively breastfeeding until the infant turn 6 months will

be eligible to participate in the trial.

After signing an informed consent, the infants will be randomized into two groups.

 $1) The \ control \ group; the \ baby \ will \ only \ be \ breastfed \ until \ the \ baby \ reaches \ the \ age \ of \ 6 \ months$ 

2) the experimental group; the baby will be breastfed and receiving vitamin D supplementation (400 IU/day)

until the baby is 6 months

URL not available

**Health Conditions** 

Health Condition(s) or Problem(s) Studied: Exclusively breastfed Full-term infants at the age 2-3 months

Keywords: Exclusively Breastfed, Full-term infants, Vitamin D supplement

Eligibility

Inclusion Criteria: Only the mothers of full-term, healthy infants who have been successfully exclusively breastfed and have an

intention to exclusively breastfeeding until the infant turn 6 months will be eligible to participate in the trial.

Gender: Both

Age Limit: Minimum: 1 Months Maximum: 3 Months

Exclusion Criteria: - Infants with congenital anomaly

- Any formula-feeding infants

Accept Healthy Volunteers: Yes

Status

Overall Recruitment Status: Completed

Key Trial Dates Study Start Date (First enrollment): 02 July 2019 Indicate Type: Actual

Design

Study Type: Interventional Primary Purpose: Treatment

Study Phase:

Intervention Model: Parallel

Number of Arms: 2

Masking: Open Label Allocation: Randomized

Control: No treatment / Standard of care

Study Endpoint Classification: N/A

Sample size

Planned sample size: 100

Actual sample size at study completion: 87

Intervantion Arm 1

Intervention name: Exclusive breastfeeding

Intervention Type : No Intervention
Intervention Classification : No treatment

Intervention Description: 1) The control group; the baby will only be breastfed until the baby reaches the

age of 6 months

Intervantion Arm 2

Intervention name: Exclusive breastfeeding and Vitamin D supplement

Intervention Type: Experimental Intervention Classification: Drug

Intervention Description : 2) the experimental group; the baby will be breastfed and receiving vitamin D

supplementation (400 IU/day) until the baby is 6 months

Outcome

**Primary Outcome** 

1. Outcome Name: Infant vitamin D level

Metric / Method of measurement : serum 25OHD level (LC-MS)

Time point: at the age of 6 months

**Secondary Outcome** 

1. Outcome Name: Infant calcium level

Metric / Method of measurement : serum calcium level

Time point: at the age of 6 months

2. Outcome Name: Infant PTH level

Metric / Method of measurement : serum PTH level

Time point: at the age of 6 months

3. Outcome Name: Infant phosphorous level

Metric / Method of measurement : serum phosphorous level

Time point: at the age of 6 months

4. Outcome Name: Infant ALP level

Metric / Method of measurement: serum ALP level

Time point: at the age of 6 months

5. Outcome Name: Mother vitamin D level

Metric / Method of measurement : serum 25OHD level (LC-MS)

Time point: when infant turn 6 months

### Location

#### Section A: Central Contact

Central Contact First Name : Chayatat Middle Name : Last Name : Ruangkit

Degree : MD Phone : 0951656605 Ext. : No Data Email : chayatatr@hotmail.com

Central Contact Backup First Name : Pornchanok Middle Name : Lastname : Wantanakorn

Degree : Phone : 0818309785 Ext. : No Data Email : joy0496@yahoo.com

#### **Section B Facility Information and Contact**

1. Site Name: Chakri Naruebodindra Medical Institute, Faculty of Medicine Ramathibodi Hospital

City: Bang phli State/Province: Samut Prakan Postal Code: 10540

Country: Thailand Recruitment Status: Completed

Facility Contact First Name : Chayatat Middle Name : Last Name : Ruangkit

Degree : MD Phone : 0951656605 Ext. : No Data Email : chayatatr@hotmail.com

Facility Contact Backup First Name : Pornchanok Middle Name : Last Name : Wantanakorn

Degree: Phone: 0818309785 Ext.: No Data Email: joy0496@yahoo.com

Investigator Name First Name : Chayatat Middle Name : Last Name : Ruangkit

Degree : MD Role : Principal Investigator

#### Section C : Contact for Public Queries (Responsible Person)

First Name : Chayatat Middle Name : Last Name : Ruangkit

Degree : MD Phone : 0951656605 Ext. : No Data Email : chayatatr@hotmail.com

Postal Address: 111 Water transfer Canal Road Tambon Bang Pla, Amphoe Bang Phli

State/Province : Samut Prakan Postal Code : 10540

Country: Thailand Official Role: Study Principal Investigator

Organization Affiliation : Ramathibodi Hospital

# $Section \ D: Contact \ for \ Scientific \ Queries \ (Responsible \ Person)$

First Name : Chayatat Middle Name : Last Name : Ruangkit

Degree : MD Phone : 0951656605 Ext. : No Data Email : chayatatr@hotmail.com

 $Postal\ Address: 111\ Water\ transfer\ Canal\ Road\ Tambon\ Bang\ Pla,\ Amphoe\ Bang\ Phli$ 

State/Province : Samut Prakan Postal Code : 10540

Country: Thailand Official Role: Study Principal Investigator

Organization Affiliation: Ramathibodi Hospital

## **Summary Results**

Date of posting of results summaries: 27 August 2021

Date of first journal publication of results: Not yet published

Baseline Characteristics: Full-term, exclusively breastfed infants were randomized into two groups at 2 months of age to continue

exclusive breastfeeding either without vitamin D supplementation (control group, 50 infant-mother pairs) or with vitamin D3 supplementation at 400 IU/day (intervention group, 50 infant-mother pairs) until 6 months

of age.

Participant Flow: At 6 months, 44 infant-mother pairs in the control group 43 infant-mother pairs in the in tervention group

complete the study.

Adverse events: None

Outcome Measures: At 6 months, the serum vitamin D (25OHD) of the infants and their mothers, serum bone marker, and

infants' growth parameters were compared between the two groups.

Brief Summary of Results: The infants' serum 250HD concentration was lower in the control group than intervention group. More

infants had vitamin D sufficiency (250HD of more than 20 ng/mL) in the intervention group than the control group. There were no significant differences in the maternal 250HD concentrations between the control and intervention groups. Serum calcium, phosphorus, intact parathyroid hormone, alkaline

phosphatase, and infants' growth parameters were comparable between the two groups.

### Deidentified Individual Participant-level Data Sharing

Plan to share IPD: Yes

Plan description: The datasets used and/or analysed during the current study are available from the corresponding author on

reasonable request.

# Publication from this study

 $\label{eq:median} \mbox{MEDLINE Identifier}: \mbox{ No Data}$   $\mbox{URL link to full text publication}: \mbox{ No Data}$