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

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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
	Completion Date (Last subject, Last visit) : 15 October 2020	Indicate Type : Actual
	Study Completion Date : 31 December 2020	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

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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

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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 25OHD concentration was lower in the control group than intervention group. More infants had vitamin D sufficiency (25OHD of more than 20 ng/mL) in the intervention group than the control group. There were no significant differences in the maternal 25OHD 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

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

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