

TCTR ID : TCTR20190622001

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 : 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 : chayatat@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

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

Intervention 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

Intervention 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

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