# 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**

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|---|---|
| First Submitted Date : | 22 June 2019 |
| First Posted Date : | 22 June 2019 |
| Last Update Posted Date : | 27 August 2021 |

**Title**

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|---|---|
| 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**

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| 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**

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|---|---|
| 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.<br>After signing an informed consent, the infants will be randomized into two groups.<br>1) The control group; the baby will only be breastfed until the baby reaches the age of 6 months<br>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**

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| 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**

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| 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<br>- Any formula-feeding infants |
| Accept Healthy Volunteers : | Yes |

**Status**

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|---|---|---|
| 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**

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|---|---|
| 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**

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| **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**

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|---|---|
| **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

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|---|---|---|---|
| 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

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|---|---|---|---|
| | 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**

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| 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**

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