TCTR ID : TCTR20220511003

OTHER ID :

Overall Recruitment Status : Pending (Not yet recruiting)

Prospective registration
This protocol was registered before enrollment of the first participant.

Tracking Information

First Submitted Date :	10 May 2022
First Posted Date :	11 May 2022
Last Update Posted Date :	11 May 2022

Title

Public Title :	A randomized controlled trial of dexamethasone 4, 5 and 6 milligrams to adverse neonatal and maternal outcomes in moderate to late preterm between 320-366 weeks of gestation
Acronym :	steroids and RDS
Scientific Title :	A randomized controlled trial of dexamethasone 4, 5 and 6 milligrams to adverse neonatal and maternal outcomes in moderate to late preterm between 320-366 weeks of gestation
Sponsor ID/ IRB ID/ EC ID :	356/2565(IRB4)
Registration Site :	Thai Clinical Trials Registry
URL :	https://www.thaiclinicaltrials.org/show/TCTR20220511003
Secondary ID :	No Secondary ID

Ethics Review

1. Board Approval :	Submitted, pending
Board Name :	Siriraj Institutional Review Board
Board Affiliation :	Board Siriraj Hospital, Mahidol university, Thailand
Board Contact :	Business Phone : 024192667 Ext. No Data Business Email : siethics@mahidol.ac.th Business Address : Human Research Protection Unit. Faculty of Medicine Siriraj Hospital, Mahidol University His Majesty the King's 80th Birthday Anniversary 5th December 2007 Building 2nd floor Room 210 2 Wang Lang Road Bangkoknoi, Bangkok 10700, Thailand

Sponsor

Source(s) of Monetary or Material Supports :	Faculty of Medicine, Siriraj Hospital, Mahidol University
Study Primary Sponsor :	Faculty of Medicine, Siriraj Hospital, Mahidol University
Responsible Party :	Name/Official Title : Department of Obstetrics and Gynaecology, Faculty of Medicine, Siriraj Hospital Organization : Mahidol University Phone : 024194777 Ext. No Data Email : saifon.cha@mahidol.ac.th
Study Secondary Sponsor :	No Study Secondary Sponsor

Protocol Synopsis

Protocol Synopsis :	High dose of steroid may result in abnormal fetal programming, abnormal hypothalamic-pituitary adrenal axis, hypertension and abnormal psychomotor development. We want to compare dexamethasone 4 and 5 mg with standard dose 6 mg on adverse maternal and neonatal outcomes.

URL not available

Health Conditions

Health Condition(s) or Problem(s) Studied :	dexamethasone 4 mg ,5 mg and 6 mg, adverse neonatal and maternal outcomes
Keywords :	dexamthasone, 4mg, 5 mg, 6 mg, adverse outcome, maternal outcomes, neonatal outcomes

Eligibility

Inclusion Criteria :	1. Pregnant women who gave birth in the gestational age of 320-366 weeks by calculating the gestational age from the menstrual history and ultrasound during the first trimester. 2. Singleton pregnancy 3. Pregnant women with preterm labor 4. Pregnant women who signed their consent to participate in the research

Gender : Female

Age Limit : Minimum : 18 Years Maximum : 50 Years

Exclusion Criteria : 1. Pregnant women under 18 years of age
2. Pregnant women who have received steroids before 32 weeks of gestation
3. Pregnant women with steroid allergy or have an infection
4. Pregnant women with gestational diabetes include gestational diabetes mellitus and pregestational diabetes mellitus.

Accept Healthy Volunteers : Yes

Status

Overall Recruitment Status : Pending (Not yet recruiting)

Key Trial Dates		
	Study Start Date (First enrollment) : 01 November 2022	Indicate Type : Anticipated
	Completion Date (Last subject, Last visit) : 31 October 2024	Indicate Type : Anticipated
	Study Completion Date : 31 January 2025	Indicate Type : Anticipated

Design

Study Type : Interventional

Primary Purpose : Health Services Research

Study Phase : Phase 2

Intervention Model : Parallel

Number of Arms : 3

Masking : Open Label

Allocation : Randomized

Control : Dose Comparison

Study Endpoint Classification : Safety/Efficacy Study

Sample size

Planned sample size : 375

Intervantion Arm 1

Intervention name : Dexamethasone 5 mg

Intervention Type : Experimental

Intervention Classification : Drug

Intervention Description : Dexamthasone 5 mg will be administrated in pregnant women 320-366 weeks of gestation.

Intervantion Arm 2

Intervention name : Dexamethasone 4 mg

Intervention Type : Experimental

Intervention Classification : Drug

Intervention Description : Dexamthasone 4 mg will be administrated in pregnant women 320-366 weeks of gestation.

Intervantion Arm 3

Intervention name : Dexamethasone 6 mg

Intervention Type : Active Comparator

Intervention Classification : Drug

Intervention Description : Dexamthasone 6 mg will be administrated in pregnant women 320-366 weeks of gestation.

Outcome

Primary Outcome

1. Outcome Name : RDS in preterm infants 320-366 weeks gestation

Metric / Method of measurement : More than 60 breaths per minute, flaring, grunting, retraction of chest, and oxygen for more than 2 hours postpartum.

Time point : at 12 months after end of the intervention

Secondary Outcome

1. Outcome Name : compare the effect of the drug 4, 5 and 6 mg dexamethasone for RDS in preterm infants 320-366 weeks gestation

Metric / Method of measurement : More than 60 breaths per minute, flaring, grunting, retraction of chest, and oxygen for more than 2 hours postpartum.

Time point : at 12 months end of the intervention

2. Outcome Name : compare the effect of the different doses of dexamethasone for adverse outcomes other than RDS in preterm infants 320-336 gestational age

Metric / Method of measurement : adverse maternal and neonatal outcomes

Time point : at 12 months end of the intervention

Location

Section A : Central Contact

Central Contact	First Name : Saifon	Middle Name :	Last Name : Chawanpaiboon
	Degree : MD	Phone : 0894436106 Ext. : No Data	Email : saifon.cha@mahidol.ac.th
Central Contact Backup	First Name : Sanitra	Middle Name :	Lastname : Anuwutnavin
	Degree : MD	Phone : 024197000 Ext. : No Data	Email : asanitra@hotmail.com

Section B Facility Information and Contact

1. Site Name : Faculty of Medicine, Siririaj Hospital, Mahidol University

	City : Bangkok	State/Province : Bangkok	Postal Code : 10700
	Country : Thailand	Recruitment Status : Pending (Not yet recruiting)	
Facility Contact	First Name : Sanitra	Middle Name :	Last Name : Anuwutnavin
	Degree : MD	Phone : 024197000 Ext. : No Data	Email : asanitra@hotmail.com
Facility Contact Backup	First Name : Saifon	Middle Name :	Last Name : Chawanpaiboon
	Degree : MD	Phone : 024197000 Ext. : No Data	Email : saifon.cha@mahidol.ac.th
Investigator Name	First Name : Saifon	Middle Name :	Last Name : Chawanpaiboon
	Degree : MD	Role : Principal Investigator	

Section C : Contact for Public Queries (Responsible Person)

First Name : Saifon	Middle Name :	Last Name : Chawanpaiboon
Degree : MD	Phone : 024197000 Ext. : No Data	Email : saifon.cha@mahidol.ac.th
Postal Address : 2 Wanglang		
State/Province : Bangkok	Postal Code : 10700	
Country : Thailand	Official Role : Study Principal Investigator	
Organization Affiliation : Faculty of Medicine, Siriraj Hospital, Mahidol University		

Section D : Contact for Scientific Queries (Responsible Person)

First Name : Saifon	Middle Name :	Last Name : Chawanpaiboon
Degree : MD	Phone : 0894436106 Ext. : No Data	Email : saifon.cha@mahidol.ac.th
Postal Address : 2 Wanglang		
State/Province : Bangkok	Postal Code : 10700	
Country : Thailand	Official Role : Study Principal Investigator	
Organization Affiliation : Faculty of Medicine, Siriraj Hospital, MAhidol University		

Deidentified Individual Participant-level Data Sharing

Plan to share IPD : Yes

Plan description : IPD and documents will be available for sharing 1 year after publication for a period of 2 years. Access to the IPD and documents will be open on the IPDShare website with registration. The information will be freely available and can be used for any purpose. There will not be any review process or no Data Use Agreement will be necessary.

Publication from this study

MEDLINE Identifier : No Data

URL link to full text publication : No Data