

**TCTR ID : TCTR20230724002**

Overall Recruitment Status : Unknown

**OTHER ID :**

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

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**Tracking Information**

First Submitted Date : 24 July 2023  
First Posted Date : 24 July 2023  
Last Update Posted Date : 25 January 2025

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**Title**

Public Title : Impact of timing from last dose of dexamethasone administration to delivery, different steroid courses, and fetal number on preterm neonatal outcomes  
Acronym : Time of ACS and RDS  
Scientific Title : Impact of timing from last dose of dexamethasone administration to delivery, different steroid courses, and fetal number on preterm neonatal outcomes  
Sponsor ID/ IRB ID/ EC ID : Si754/2023  
Registration Site : Thai Clinical Trials Registry  
URL : <https://www.thaiclinicaltrials.org/show/TCTR20230724002>  
Secondary ID : No Secondary ID

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**Ethics Review**

1. Board Approval : Submitted, approved  
Approval Number : COA [Si754/2023].  
Date of Approval : 29 September 2023  
Board Name : Human Research Protection Unit  
Board Affiliation : Faculty of Medicine Siriraj Hospital, Mahidol University  
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

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**Sponsor**

Source(s) of Monetary or Material Supports : Faculty of Medicine, Siriraj Hospital  
Study Primary Sponsor : Faculty of Medicine, Siriraj Hospital  
Responsible Party : Name/Official Title : Maternal and Fetal Medicine, Department of Obstetrics and Gynaecology, Siriraj Hospital  
Organization : Siriraj Hospital, Mahidol University  
Phone : 024192667 Ext. No Data  
Email : siethics@mahidol.ac.th  
Study Secondary Sponsor : No Study Secondary Sponsor

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**Protocol Synopsis**

Protocol Synopsis : Effect of dexamethasone administration from last dose to delivery affect to the incidence of respiratory distress syndrome in preterm delivery. Pharmacokinetics and pharmacodynamics of dexamethasone may affect to the incomplete, complete and more than one course of dexamethasone treatment. We want to investigate the effect of time to delivery to adverse outcomes of fetus and mothers after the last dose of dexamethasone administration. Neonatal outcomes including respiratory distress syndrome, intraventricular hemorrhage and necrotizing enterocolitis will be measured between those 3 groups of intervention.

URL not available

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**Health Conditions**

Health Condition(s) or Problem(s) Studied : adverse neonatal and maternal outcomes  
Keywords : time to delivery dexamethasone course of ACS

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**Eligibility**

Inclusion Criteria : 1. Singleton babies born prematurely during 24 weeks -36weeks 6 days of gestation  
2. Mothers have a history of dexamethasone administration before preterm delivery

Gender : Female

Age Limit : Minimum : 12 Years Maximum : 50 Years

Exclusion Criteria : Premature infants whose mothers had not received prenatal steroid injections.

Accept Healthy Volunteers : No

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**Status**

Overall Recruitment Status : Unknown

Key Trial Dates Study Start Date (First enrollment) : 01 October 2023 Indicate Type : Anticipated

Completion Date (Last subject, Last visit) : 30 April 2025 Indicate Type : Anticipated

Study Completion Date : 30 June 2025 Indicate Type : Anticipated

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**Design**

Study Type : Observational

Primary Purpose : Health Services Research

Number of Groups : 3

Study Endpoint Classification : N/A

Sample size

Planned sample size : 1800

Actual sample size at study completion :

Observation Group 1

Group name : Control group

Group Description : complete course of ACS

Observation Group 2

Group name : study group

Group Description : incomplete course of ACS

Observation Group 3

Group name : study group

Group Description : more than one courses of ACS

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**Outcome****Primary Outcome**

1. Outcome Name : respiratory problems

Metric / Method of measurement : respiratory rate/ beats per minutes

Time point : 2 hours after delivery

**Secondary Outcome**

1. Outcome Name : respiratory distress in premature infants, early and late preterm

Metric / Method of measurement : respiratory rate/ beats per minute

Time point : 2 hours after delivery

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**Location****Section A : Central Contact**

Central Contact First Name : Saifon

Middle Name :

Last Name : Chawanpaiboon

Degree : M.D.

Phone : 024197000 Ext. : No Data

Email : saifon.cha@mahidol.ac.th

Central Contact Backup First Name : Monsak

Middle Name :

Lastname : Chuchotiros

Degree : M.D.

Phone : 024197000 Ext. : No Data

Email : monsak.chu@mahidol.ac.th

**Section B Facility Information and Contact**

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

City : Bangkoknoi

State/Province : Bangkok

Postal Code : 10700

Country : Thailand	Recruitment Status : Pending (Not yet recruiting)	
<b>Facility Contact</b>	First Name : Saifon	Middle Name : Last Name : Chawanpaiboon
	Degree : M.D.	Phone : 024197000 Ext. : No Data Email : saifon.cha@mahidol.ac.th
<b>Facility Contact Backup</b>	First Name : Monsak	Middle Name : Last Name : Chuchotiros
	Degree : M.D.	Phone : 024197000 Ext. : No Data Email : monsak.chu@mahidol.ac.th
<b>Investigator Name</b>	First Name : Saifon	Middle Name : Last Name : Chawanpaiboon
	Degree : M.D.	Role : Principal Investigator
<b>Section C : Contact for Public Queries (Responsible Person)</b>		
	First Name : Saifon	Middle Name : Last Name : Chawanpaiboon
	Degree : M.D.	Phone : 024197000 Ext. : No Data Email : saifon.cha@mahidol.ac.th
	Postal Address : 2 Wanglang, Siriraj, Bangkoknoi	
	State/Province : Bangkok	Postal Code : 10700
	Country : Thailand	Official Role : Study Principal Investigator
	Organization Affiliation : Faculty of Medicine, Siriraj Hospital, Mahidol University	
<b>Section D : Contact for Scientific Queries (Responsible Person)</b>		
	First Name : Saifon	Middle Name : Last Name : Chawanpaiboon
	Degree : M.D.	Phone : 024197000 Ext. : No Data Email : saifon.cha@mahidol.ac.th
	Postal Address : 2 Wanglang, Siriraj, Bangkoknoi	
	State/Province : Bangkok	Postal Code : 10700
	Country : Thailand	Official Role : Study Principal Investigator
	Organization Affiliation : Faculty of Medicine, Siriraj Hospital, Mahidol University	

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**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.

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**Publication from this study**

MEDLINE Identifier : No Data

URL link to full text publication : No Data

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