TCTR ID : TCTR20241102001

OTHER ID :

Overall Recruitment Status : Completed **(No Results)**

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

Tracking Information

First Submitted Date :	01 November 2024
First Posted Date :	02 November 2024
Last Update Posted Date :	29 November 2025

Title

Public Title :	Comparison of azithromycin and erythromycin on prolong latency period in PPROM before 34 weeks of gestation
Acronym :	ATBs and PPROM
Scientific Title :	Azithromycin and erythromycin on prolong latency period in PPROM
Sponsor ID/ IRB ID/ EC ID :	Si000/2024
Registration Site :	Thai Clinical Trials Registry
URL :	https://www.thaiclinicaltrials.org/show/TCTR20241102001
Secondary ID :	No Secondary ID

Ethics Review

1. Board Approval :	Submitted, pending
Board Name :	Human Research Protection Unit. Faculty of Medicine Siriraj Hospital, Mahidol University
Board Affiliation :	Mahidol University, Thailand
Board Contact :	Business Phone : 024192667 Ext. No Data
	Business Email : siethics@mahidol.ac.th
	Business Address : His Majesty the King's 80th Birthday Anniversary 5th December 2007 Building 2nd floor Room 210 2 Wang Lang Road Bangkoknoi, Bangkok 10700, Thailand FAX : 0 2411 0162

Sponsor

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

Protocol Synopsis

Protocol Synopsis :	To compare the effect of azithromycin and erythromycin on prolonging latency period at different gestational ages: 1. Extremely preterm (24-< 28 weeks of gestation) 2. Very preterm (28-< 32 weeks of gestation) and 3. Moderate preterm (32-<34 weeks of gestation)

URL not available

Health Conditions

Health Condition(s) or Problem(s) Studied :	Prolong latency period of pregnancy maternal adverse outcomes neonatal adverse outcomes
Keywords :	azithromycin, erythromycin, prolong latency period, neonatal adverse outcomes, maternal adverse outcomes

Eligibility

Inclusion Criteria :	Azithromycin group 1. Pregnant women with rupture of membranes between 24-<34 weeks of gestation 2. Pregnant women who received ampicillin 2 g IV every 6 hours and azithromycin 1 g for the first 48 hours followed by amoxycillin 500 mg 3 times daily for 5 days until 7 days to prolong the latency period

Erythromycin group
1. Pregnant women with rupture of membranes between 24-<34 weeks of gestation
2. Pregnant women who received ampicillin 2 g IV every 6 hours and erythromycin 250 mg orally every 6 hours for the first 48 hours followed by amoxycillin 250 mg 3 times daily and erythromycin 250 mg 4 times daily for 5 days until 7 days to prolong the latency period

Gender : Female

Age Limit : Minimum : 18 Years Maximum : 50 Years

Exclusion Criteria : 1. Pregnant women who are not taking drugs to prolong the latency period
2. Pregnant women who are contraindicated to take drugs to prolong the latency period

Accept Healthy Volunteers : No

Status

Overall Recruitment Status : Completed

Key Trial Dates

Study Start Date (First enrollment) : 30 January 2025	Indicate Type : Actual
Completion Date (Last subject, Last visit) : 01 November 2025	Indicate Type : Actual
Study Completion Date : 28 November 2025	Indicate Type : Actual

Design

Study Type : Observational

Primary Purpose : Health Services Research

Number of Groups : 2

Study Endpoint Classification : N/A

Sample size

Planned sample size : 720

Actual sample size at study completion :

Observation Group 1

Group name : azithromycin

Group Description : Pregnant women with rupture of membranes between 24-34 weeks of gestation who received ampicillin 2 g IV every 6 hours and azithromycin 1 g for the first 48 hours followed by amoxycillin 500 mg 3 times daily for 5 days until 7 days to prolong the latency period

Observation Group 2

Group name : erythromycin

Group Description : Pregnant women with rupture of membranes between 24-34 weeks of gestation who received ampicillin 2 g IV every 6 hours and erythromycin 250 mg orally every 6 hours for the first 48 hours followed by amoxycillin 250 mg 3 times daily and erythromycin 250 mg 4 times daily for 5 days until 7 days to prolong the latency period

Outcome

Primary Outcome

1. Outcome Name : prolong latency period

Metric / Method of measurement : days

Time point : 7 days

Secondary Outcome

1. Outcome Name : adverse maternal outcomes

Metric / Method of measurement : intensive care unit admission

Time point : 7 days

2. Outcome Name : adverse neonatal outcomes

Metric / Method of measurement : neonatal intensive care unit admission

Time point : 7 days

Location

Section A : Central Contact

Central Contact First Name : Julaporn Middle Name : Last Name : Pooliam

This document was created on 02 November 2026 at 02:00 (GMT+7).

	Degree : M.S.	Phone : 024194777 Ext. : No Data	Email : juscma@hotmail.com
Central Contact Backup	First Name : Saifon	Middle Name :	Lastname : Chawanpaiboon
	Degree : M.D.	Phone : 024194777 Ext. : No Data	Email : saifon.cha@mahidol.ac.th

Section B Facility Information and Contact

1.	Site Name : Faculty of Medicine Siriraj Hopsital, Mahidol university		
	City : Bangkoknoi	State/Province : Bangkok	Postal Code : 10700
	Country : Thailand	Recruitment Status : Pending (Not yet recruiting)	
Facility Contact	First Name : Saifon	Middle Name :	Last Name : Chawanpaiboon
	Degree : M.D.	Phone : 0894436101 Ext. : No Data	Email : saifonchawanpaiboon@gmail.com
Facility Contact Backup	First Name : Julaporn	Middle Name :	Last Name : Pooliam
	Degree : M.S.	Phone : 024194777 Ext. : No Data	Email : juscma@hotmail.com
Investigator Name	First Name : Saifon	Middle Name :	Last Name : Chawanpaiboon
	Degree : M.D.	Role : Principal Investigator	

Section C : Contact for Public Queries (Responsible Person)

First Name : Saifon	Middle Name :	Last Name : Chawanpaiboon
Degree : M.D.	Phone : 024194777 Ext. : No Data	Email : saifon.cha@mahidol.ac.th
Postal Address : 2 Wanglung, Siriraj, Bangkoknoi		
State/Province : Thailand	Postal Code : 10700	
Country : Thailand	Official Role : Study Principal Investigator	
Organization Affiliation : Siriraj Hospital, Mahidol University		

Section D : Contact for Scientific Queries (Responsible Person)

First Name : Saifon	Middle Name :	Last Name : Chawanpaiboon
Degree : M.D.	Phone : 0894436101 Ext. : No Data	Email : saifon.cha@mahidol.ac.th
Postal Address : 2 Wanglung, Siriraj, Bangkoknoi		
State/Province : Thailand	Postal Code : 10700	
Country : Thailand	Official Role : Study Principal Investigator	
Organization Affiliation : Siriraj Hospital, Mahidol University		

Summary Results

Date of posting of results summaries : Summary results not yet available

Date of first journal publication of results : Not yet published

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.

Publication from this study

MEDLINE Identifier : No Data

URL link to full text publication : No Data