

**TCTR ID : TCTR20241102001**

Overall Recruitment Status : Completed (No Results)

**OTHER ID :**

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

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**Tracking Information**

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

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**Title**

Public Title : Comparison of azithromycin and erythromycin on prolong latency period in PPRM before 34 weeks of gestation  
Acronym : ATBs and PPRM  
Scientific Title : Azithromycin and erythromycin on prolong latency period in PPRM  
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

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**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

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**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 Siriraj Hospital, Mahidol University  
Phone : 024194777 Ext. No Data  
Email : saifon.cha@mahidol.ac.th  
Study Secondary Sponsor : No Study Secondary Sponsor

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**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**

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**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

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**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 amoxicillin 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 amoxicillin 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

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**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

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**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 amoxicillin 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 amoxicillin 250 mg 3 times daily and erythromycin 250 mg 4 times daily for 5 days until 7 days to prolong the latency period

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**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

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**Location**

**Section A : Central Contact**

Central Contact First Name : Julaporn

Middle Name :

Last Name : Pooliam

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 Hospital, 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

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**Summary Results**

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

Date of first journal publication of results : Not yet published

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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.

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**Publication from this study**

MEDLINE Identifier : No Data

URL link to full text publication : No Data

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