TCTR ID : TCTR20250627001

OTHER ID :

Overall Recruitment Status : Completed **(Has Results)**

Retrospective registration
This protocol was registered after enrollment of the first participant.

Tracking Information

First Submitted Date :	12 June 2025
First Posted Date :	27 June 2025
Last Update Posted Date :	27 June 2025

Title

Public Title :	Comparison Results of Modified Enhanced Recovery After Surgery to Standard Protocol for Patients with Emergency Cesarean Delivery: A randomized controlled trial
Acronym :	mERAS
Scientific Title :	Comparison Results of Modified Enhanced Recovery After Surgery to Standard Protocol for Patients with Emergency Cesarean Delivery: A randomized controlled trial
Sponsor ID/ IRB ID/ EC ID :	COA No.210
Registration Site :	Thai Clinical Trials Registry
URL :	https://www.thaiclinicaltrials.org/show/TCTR20250627001
Secondary ID :	No Secondary ID

Ethics Review

1. Board Approval :	Submitted, approved
Approval Number :	COA No.210
Date of Approval :	11 August 2023
Board Name :	Phayao Hospital Ethics Committee of Human Research
Board Affiliation :	Phayao Hospital, Thailand
Board Contact :	Business Phone : 0871772061 Ext. No Data
	Business Email : Scorpio.fai55@gmail.com
	Business Address : Medical education center Phayao hospital

Sponsor

Source(s) of Monetary or Material Supports :	N/A
Study Primary Sponsor :	N/A
Responsible Party :	Name/Official Title : Pornpimon Nittiwatthanawit
	Organization : Phayao Hospital
	Phone : 0871772061 Ext. No Data
	Email : Scorpio.fai55@gmail.com
Study Secondary Sponsor :	No Study Secondary Sponsor

Protocol Synopsis

Protocol Synopsis :	This study aims to evaluate postoperative recovery in pregnant women who underwent emergency CD. The recovery process was assessed using the Quality of Recovery questionnaire (QoR-35, Thai version) and pain scores measured by the Visual Analog Scale (VAS), comparing the modified ERAS (mERAS) protocol to the standard protocol.

URL not available

Health Conditions

Health Condition(s) or Problem(s) Studied :	Emergency cesarean section
Keywords :	mERAS, emergency cesarean section

Eligibility

Inclusion Criteria :	1. Gestational age between 28 and 42 weeks underwent emergency cesarean section at the Department of Obstetrics and Gynecology, a medical education center within Phayao Hospital, Thailand, between August 2023 and December 2023

2. Able to complete the questionnaire in Thai

Gender : Female

Age Limit : Minimum : 15 Years Maximum : 45 Years

Exclusion Criteria : 1. High-risk obstetric comorbiditiessuch as placenta previa, placenta accreta spectrum, preeclampsia with severe features, and chorioamnionitis
2. Intraoperative complications such as postpartum hemorrhage, bowel or bladder injuries, and sepsis
3. Allergies to acetaminophen or NSAIDs

Accept Healthy Volunteers : Yes

Status

Overall Recruitment Status : Completed

Key Trial Dates		
	Study Start Date (First enrollment) : 01 August 2023	Indicate Type : Actual
	Completion Date (Last subject, Last visit) : 31 December 2023	Indicate Type : Actual
	Study Completion Date : 31 December 2023	Indicate Type : Actual

Design

Study Type : Interventional

Primary Purpose : Treatment

Study Phase : Phase 3

Intervention Model : Parallel

Number of Arms : 2

Masking : Masked Masked Role : Allocation concealment, Outcome Assessor, Statistician

Allocation : Randomized

Control : No treatment / Standard of care

Study Endpoint Classification : Efficacy Study

Sample size

Planned sample size : 50

Actual sample size at study completion : 50

Intervantion Arm 1

Intervention name : Modified Enhanced Recovery After Surgery

Intervention Type : Experimental

Intervention Classification : Other

Intervention Description : A modified ERAS (mERAS) protocol focused on postoperative elements such as early oral intake, multimodal oral analgesia, early mobilization, and timely removal of urinary catheters can be safely adapted for emergency cesarean section

Intervantion Arm 2

Intervention name : Standard care

Intervention Type : No Intervention

Intervention Classification : No treatment

Intervention Description : a gradual postoperative feeding strategy, progressing from small sips of water to liquids, then to a soft diet, and ultimately to a regular diet once bowel function returns typically 8 to 20 hours after surgery

Outcome

Primary Outcome

1. Outcome Name : 48-hour postoperative Visual analogue score

Metric / Method of measurement : Visual analogue score

Time point : 48 hours

2. Outcome Name : 24-hour quality of recovery-35 (QoR-35) Thai version score

Metric / Method of measurement : Thai quality of recovery-35 (QoR-35) score

Time point : 24 hours

Secondary Outcome

1. Outcome Name : Length of hospital stay
Metric / Method of measurement : hours
Time point : within 72 hours
2. Outcome Name : Duration until onset of burping symptoms
Metric / Method of measurement : hours
Time point : within 72 hours
3. Outcome Name : Duration until onset of flatulence symptoms
Metric / Method of measurement : hours
Time point : within 72 hours

Location

Section A : Central Contact

Central Contact	First Name : Pornpimon	Middle Name :	Last Name : Nittiwatthanawit
	Degree :	Phone : 054409300 Ext. : No Data	Email : Scorpio.fai55@gmail.com
Central Contact Backup	First Name : Pornnapa	Middle Name :	Lastname : Suriyachai
	Degree :	Phone : 054409300 Ext. : No Data	Email : Whan76_1@hotmail.com

Section B Facility Information and Contact

1.	Site Name : Medical Education Center Phayao Hospital		
	City : Mueang Phayao	State/Province : Phayao	Postal Code : 56000
	Country : Thailand	Recruitment Status : Completed	
Facility Contact	First Name : Pornpimon	Middle Name :	Last Name : Nittiwatthanawit
	Degree :	Phone : 054409300 Ext. : No Data	Email : Scorpio.fai55@gmail.com
Facility Contact Backup	First Name : Patchamas	Middle Name :	Last Name : Kakaew
	Degree :	Phone : 054409300 Ext. : No Data	Email : Patchamas.k@gmail.com
Investigator Name	First Name : Pornpimon	Middle Name :	Last Name : Nittiwatthanawit
	Degree :	Role : Principal Investigator	

Section C : Contact for Public Queries (Responsible Person)

First Name : Pornpimon	Middle Name :	Last Name : Nittiwatthanawit
Degree : No Data	Phone : 054409300 Ext. : No Data	Email : Scorpio.fai55@gmail.com
Postal Address : Medical education center Phayao hospital 269 Moo 11 bantom subdistrict, Mueang district		
State/Province : Phayao	Postal Code : 56000	
Country : Thailand	Official Role : Study Principal Investigator	
Organization Affiliation : Medical Education Center Phayao Hospital		

Section D : Contact for Scientific Queries (Responsible Person)

First Name : Pornpimon	Middle Name :	Last Name : Nittiwatthanawit
Degree : No Data	Phone : 054409300 Ext. : No Data	Email : Scorpio.fai55@gmail.com
Postal Address : Medical education center Phayao hospital 269 Moo 11 bantom subdistrict, Mueang district		
State/Province : Phayao	Postal Code : 56000	
Country : Thailand	Official Role : Study Principal Investigator	
Organization Affiliation : Medical education center Phayao hospital		

Summary Results

Date of posting of results summaries : 01 April 2025
Date of first journal publication of results : Not yet published
Baseline Characteristics : The data include age, body mass index (BMI), Underlying conditions included chronic hypertension, hyperthyroidism, and pregestational diabetes mellitus. Antenatal complications consisted of gestational diabetes mellitus, preeclampsia without severe features, isolated maternal fever, and acute gastroenteritis. The primary indications for cesarean delivery, anesthetic agent, operative time, average fetal weight, and estimated blood loss.
Participant Flow : Assessed for eligibility (n 53) Excluded (n 3): Placenta previa 1, Preeclampsia with severe feature 2 Randomized (n 50): mERAS 25, standard care 25
Adverse events : none
Outcome Measures : The primary outcomes were the 24-hour QoR-35 score and the 48-hour VAS score. Additional parameters,

	including postoperative hospitalization duration, opioid use, and the onset of gastrointestinal functions, were also assessed. The analysis further considered postoperative complications such as fever, wound dehiscence, and readmission
Brief Summary of Results :	The mERAS group showed a significant reduction in 48-hour postoperative VAS scores (p 0.024). No significant differences were observed between the two groups in the 24-hour or immediate timeframe assessment across all parameters. Additionally, the mERAS group experienced shorter hospitalization (p 0.017), earlier onset of burping (p 0.049), and earlier onset of flatulence (p 0.011).

Deidentified Individual Participant-level Data Sharing

Plan to share IPD :	No
Reason :	Fear of inappropriate use of data

Publication from this study

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