

TCTR ID : TCTR20241205001

Overall Recruitment Status : Completed (Has Results)

OTHER ID :

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

Tracking Information

First Submitted Date : 11 November 2024
First Posted Date : 05 December 2024
Last Update Posted Date : 04 August 2026

Title

Public Title : Intravenous nalbuphine for prevention of intrathecal morphine-induced nausea and vomiting in patients undergoing cesarean section : A double-blind, randomized controlled trial
Acronym : No Data
Scientific Title : Intravenous nalbuphine for prevention of intrathecal morphine-induced nausea and vomiting in patients undergoing cesarean section : A double-blind, randomized controlled trial
Sponsor ID/ IRB ID/ EC ID : MTU-EC-AN1-130/66
Registration Site : Thai Clinical Trials Registry
URL : <https://www.thaiclinicaltrials.org/show/TCTR20241205001>
Secondary ID : No Secondary ID

Ethics Review

1. Board Approval : Submitted, approved
Approval Number : 229/2023
Date of Approval : 12 October 2023
Board Name : The Human Research Ethics Committee of Thammasat University (Medicine)
Board Affiliation : Thammasat University, Thailand
Board Contact : Business Phone : 6625644444 Ext. 7535
Business Email : ec.medtu@gmail.com
Business Address : 99/209 Moo 18, Paholyothin Road, Amphur Klongluang, Pathumthani. Thailand 12120

Sponsor

Source(s) of Monetary or Material Supports : thammasat University
Study Primary Sponsor : thammasat University
Responsible Party : Name/Official Title : Noppasorn Vissanu Wong
Organization : Faculty of Medicine, Thammasat University
Phone : 0951955497 Ext. No Data
Email : noppasorn.viss@gmail.com
Study Secondary Sponsor : No Study Secondary Sponsor

Protocol Synopsis

Protocol Synopsis : Primary outcome
Incidence of nausea and vomiting in first 24 hours after spinal anesthesia with intrathecal morphine
Secondary outcomes
Severity of nausea and vomiting at PACU, 6th and 24th hour
Pruritus score at PACU, 6th and 24th hour
Sedation score 0-3 at PACU, 6th and 24th hour
Pain score at 6th and 24th hour
Other analgesic and dose received with first 24 hours
Incidence of respiratory depression within first 24 hours

Research methodology
NPO and IV maintenance fluid
Spinal anesthesia procedure : 0.5% hyperbaric marcaine with Morphine 0.2 mg - total 2.2 ml with Quincke needle No. 27
Adequate level for Cesarean section at T4 level
After fetal delivery --> Oxytocin 3 IU IV and Research medication
(N group : Nalbuphine (1mg/ml) 4 ml

P group : Placebo : NSS 4 ml)
Intraoperative management
if Nausea and vomiting with SBP > 100 mmHg or within 20% of BP baseline, giving Ondansetron 0.1 mg/kg and Exclude from the study
Standard postoperative Care at PACU

URL not available

Health Conditions

Health Condition(s) or Problem(s) Studied : intrathecal morphine-induced nausea and vomiting in patients undergoing cesarean section

Keywords : intrathecal morphine-induced nausea and vomiting, cesarean section

Eligibility

Inclusion Criteria : 1. Elective cesarean section under spinal anesthesia
2. older than 18 years old

Gender : Female

Age Limit : Minimum : 18 Years Maximum : 45 Years

Exclusion Criteria : 1. Patients with known allergy to research drugs such as nalbuphine, bupivacaine or morphine
2. Medical complications eg heart diseases, diabetes, hypertension, renal or hepatic disease, obesity >=100 kilograms
3. Obstetrical complications eg twins or multiple gestation, pre-eclampsia, IUGR(intra-uterine growth retardation), placenta previa
4. History of postoperative nausea and vomiting (PONV), motion sickness or passive smoker
5. Patient with known history of drug abuse
6. Unwilling to participate in the study

Accept Healthy Volunteers : No

Status

Overall Recruitment Status : Completed

Key Trial Dates	Study Start Date (First enrollment) : 07 December 2024	Indicate Type : Actual
	Completion Date (Last subject, Last visit) : 15 February 2025	Indicate Type : Actual
	Study Completion Date : 20 February 2025	Indicate Type : Actual

Design

Study Type : Interventional

Primary Purpose : Prevention

Study Phase : Phase 3

Intervention Model : Parallel

Number of Arms : 2

Masking : Masked Masked Role : Allocation concealment, Subject, Caregiver, Investigator, Statistician

Allocation : Randomized

Control : Placebo

Study Endpoint Classification : Efficacy Study

Sample size

Planned sample size : 180

Actual sample size at study completion : 167

Intervention Arm 1

Intervention name : nalbuphine

Intervention Type : Active Comparator

Intervention Classification : Drug

Intervention Description : nalbuphine 4 mg IV

Intervention Arm 2

Intervention name : placebo

Intervention Type : Placebo Comparator
Intervention Classification : No treatment
Intervention Description : NSS 4 ml IV

Outcome

Primary Outcome

1. Outcome Name : event rate of nausea and vomiting
Metric / Method of measurement : event rate
Time point : postoperative 1,6,24 hr

Secondary Outcome

1. Outcome Name : severity of nausea
Metric / Method of measurement : nausea and vomiting score 0-3
Time point : postoperative 1,6,24 hr
2. Outcome Name : severity of pruritus
Metric / Method of measurement : pruritus score 0-3
Time point : postoperative 1,6,24 hr
3. Outcome Name : sedation score
Metric / Method of measurement : sedation score 0-3
Time point : postoperative 1,6,24 hr
4. Outcome Name : pain score
Metric / Method of measurement : Numeric pain score
Time point : postoperative 6,24 hr

Location

Section A : Central Contact

Central Contact	First Name : Preeyaphan	Middle Name :	Last Name : Arunakul
	Degree : MD	Phone : 0816635144 Ext. : No Data	Email : kpreeyap@tu.ac.th
Central Contact Backup	First Name : Noppasorn	Middle Name :	Lastname : Vissanu Wong
	Degree : MD	Phone : 029778217 Ext. : No Data	Email : noppasorn.viss@gmail.com

Section B Facility Information and Contact

1. Site Name : Department of Anesthesiology, Faculty of Medicine, Thammasat University
City : pathumthani State/Province : pathumthani Postal Code : 12121
Country : Thailand Recruitment Status : Completed

Facility Contact	First Name : Preeyaphan	Middle Name :	Last Name : Arunakul
	Degree : MD	Phone : 0816635144 Ext. : No Data	Email : kpreeyap@tu.ac.th

Facility Contact Backup	First Name : Noppasorn	Middle Name :	Last Name : Vissanu Wong
	Degree : MD	Phone : 029778214 Ext. : No Data	Email : noppasorn.viss@gmail.com

Investigator Name	First Name : Preeyaphan	Middle Name :	Last Name : Arunakul
	Degree : MD	Role : Principal Investigator	

Section C : Contact for Public Queries (Responsible Person)

First Name : Preeyaphan	Middle Name :	Last Name : Arunakul
Degree : MD	Phone : 0816635144 Ext. : No Data	Email : kpreeyap@tu.ac.th
Postal Address : 99/209 moo 18, Paholyothin Road, Amphur Klongluang		
State/Province : Pathumthani	Postal Code : 12120	
Country : Thailand	Official Role : Study Principal Investigator	
Organization Affiliation : Department of Anesthesiology, Faculty of Medicine, Thammasat University		

Section D : Contact for Scientific Queries (Responsible Person)

First Name : Preeyaphan	Middle Name :	Last Name : Arunakul
Degree : MD	Phone : 0816635144 Ext. : No Data	Email : kpreeyap@tu.ac.th
Postal Address : 99/209 moo 18, Paholyothin Road, Amphur Klongluang		
State/Province : Pathumthani	Postal Code : 12120	

Country : Thailand

Official Role : Study Principal Investigator

Organization Affiliation : Department of Anesthesiology, Faculty of Medicine, Thammasat university

Summary Results

Date of posting of results summaries : 26 January 2026

Date of first journal publication of results : Not yet published

Baseline Characteristics : Patients undergoing caesarean section under spinal anesthesia with 0.2 mg of intrathecal morphine

Participant Flow : One hundred and eighty patients were recruited and randomized into 2 groups by block of 4 computer-generated randomization. One hundred and sixty-seven patients were analyzed.

Adverse events : No respiratory depression was observed in this study.

Outcome Measures : Primary outcome was event rate of PONV in the first 24 hours. Secondary outcomes were severity of nausea and vomiting, pain scores, number of patients with pruritus and respiratory depression.

Brief Summary of Results : In 24 hours, number of patients with nausea vomiting in nalbuphine group was lower than control group (23.81% VS 42.17%). Ten percents of patients in nalbuphine group had nausea vomiting required treatment in the first 6 hours compared to 14.45% in control group. IV nalbuphine could lower event rate of PONV 24 hours after spinal anesthesia with 0.2 mg of ITMO in patients underwent caesarean section.

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
