TCTR ID : TCTR20260508005

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 :	07 May 2026
First Posted Date :	08 May 2026
Last Update Posted Date :	08 May 2026

Title

Public Title :	Efficacy and safety of intrathecal morphine compared to peripheral nerve blocks in patients underwent foot and ankle surgery: A propensity score analysis
Acronym :	No Data
Scientific Title :	Efficacy and safety of intrathecal morphine compared to peripheral nerve blocks in patients underwent foot and ankle surgery: A propensity score analysis
Sponsor ID/ IRB ID/ EC ID :	MTU-EC-AN-6-152/63
Registration Site :	Thai Clinical Trials Registry
URL :	https://www.thaiclinicaltrials.org/show/TCTR20260508005
Secondary ID :	No Secondary ID

Ethics Review

1. Board Approval :	Submitted, approved
Approval Number :	179/2563
Date of Approval :	20 August 2020
Board Name :	Human Research Ethics Committee of Thammasat University No.1 (Faculty of Medicine)
Board Affiliation :	Faculty of Medicine, Thammasat University
Board Contact :	Business Phone : 029269704 Ext. 7535
	Business Email : ec.medtu@gmail.com
	Business Address : 99/209 Moo 18, Paholyotin Road, Auphur Klongluang, Pathumthani, Thailand 12120

Sponsor

Source(s) of Monetary or Material Supports :	N/A
Study Primary Sponsor :	N/A
Responsible Party :	Name/Official Title : Department of Anesthesiology, Faculty of Medicine
	Organization : Thammasat University
	Phone : 0816635144 Ext. No Data
	Email : preeyaphan@hotmail.com
Study Secondary Sponsor :	No Study Secondary Sponsor

Protocol Synopsis

Protocol Synopsis :	This retrospective data was collected from medical records of patients who underwent foot ankle surgery between 2013-2020. Patients underwent foot ankle surgery under spinal anesthesia combined with either intrathecal morphine or Peripheral nerve blocks. Intrathecal morphine 0.1 mg was given along with 0.5% hyperbaric or isobaric bupivacaine. All the peripheral nerve blocks were done before spinal anesthesia by experienced anesthesiologists under US guidance. We compared the efficacy of 0.1 mg intrathecal morphine in postoperative pain control to US-guided peripheral nerve blocks using propensity score analysis.

URL not available

Health Conditions

Health Condition(s) or Problem(s) Studied :	Postoperative pain after foot ankle surgery.
Keywords :	Foot ankle surgery Spinal anesthesia Intrathecal morphine Peripheral nerve blocks

Eligibility

Inclusion Criteria :	medical records of patients who underwent foot ankle surgery between 2013-2020. Patients underwent foot

ankle surgery under spinal anesthesia combined with either intrathecal morphine or peripheral nerve blocks.

Gender : Both

Age Limit : Minimum : 15 Years Maximum : 85 Years

Exclusion Criteria : NA

Accept Healthy Volunteers : No

Status

Overall Recruitment Status : Completed

Key Trial Dates	Study Start Date (First enrollment) : 11 August 2020	Indicate Type : Actual
	Completion Date (Last subject, Last visit) : 22 December 2024	Indicate Type : Actual
	Study Completion Date : 22 April 2025	Indicate Type : Actual

Design

Study Type : Observational

Primary Purpose : Treatment

Number of Groups : 2

Study Endpoint Classification : N/A

Sample size

Planned sample size : 114

Actual sample size at study completion : 114

Observation Group 1

Group name : SBPNB

Group Description : spinal anesthesia + US-guided peripheral nerve blocks

Observation Group 2

Group name : SBMO

Group Description : spinal anesthesia + Intrathecal morphine 0.1 mg

Outcome

Primary Outcome

1. Outcome Name : proportion of patients who required rescue analgesic medication during the first postoperative 24 hours

Metric / Method of measurement : number of patients required rescue analgesic within the first 24 hours

Time point : 24 hours

Secondary Outcome

1. Outcome Name : mean pain scores in patients at the 6th , 12th , and 24th hours after surgery

Metric / Method of measurement : Numerical rating scale (NRS)

Time point : 6,12,24 hours

2. Outcome Name : Side effects of intrathecal morphine

Metric / Method of measurement : number of patients with side effects required treatment

Time point : 6,12,24 hours

Location

Section A : Central Contact

Central Contact	First Name : preeyaphan	Middle Name :	Last Name : arunakul
	Degree : M.D.	Phone : 0816635144 Ext. : No Data	Email : preeyaphan@hotmail.com
Central Contact Backup	First Name : marut	Middle Name :	Lastname : arunakul
	Degree : M.D.	Phone : 0818199455 Ext. : No Data	Email : kai892@hotmail.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 : M.D.	Phone : 0816635144 Ext. : No Data	Email : preeyaphan@hotmail.com
Facility Contact Backup	First Name : Marut	Middle Name :	Last Name : arunakul
	Degree : M.D.	Phone : 0818199455 Ext. : No Data	Email : kai892@hotmail.com
Investigator Name	First Name : preeyaphan	Middle Name :	Last Name : arunakul
	Degree : M.D.	Role : Principal Investigator	

Section C : Contact for Public Queries (Responsible Person)

First Name : preeyaphan	Middle Name :	Last Name : arunakul
Degree : M.D.	Phone : 0816635144 Ext. : No Data	Email : preeyaphan@hotmail.com
Postal Address : Department of Anesthesiology Faculty of Medicine, Thammasat University		
State/Province : Pathum thani	Postal Code : 12121	
Country : Thailand	Official Role : Study Principal Investigator	
Organization Affiliation : Thammasat University		

Section D : Contact for Scientific Queries (Responsible Person)

First Name : preeyaphan	Middle Name :	Last Name : arunakul
Degree : M.D.	Phone : 0816635144 Ext. : No Data	Email : preeyaphan@hotmail.com
Postal Address : Department of Anesthesiology Faculty of Medicine, Thammasat University		
State/Province : Pathumthani	Postal Code : 12120	
Country : Thailand	Official Role : Study Principal Investigator	
Organization Affiliation : Thammasat University		

Summary Results

Date of posting of results summaries :	30 May 2025
Date of first journal publication of results :	Not yet published
Baseline Characteristics :	Patients who received spinal anesthesia and peripheral nerve blocks for postoperative analgesia and patients who received spinal anesthesia and 0.1 mg of intrathecal morphine. As selection bias and imbalance of prognostic determinants are likely to occur in this observational, non-randomized therapeutic research, we performed a propensity score matching between the 2 groups before the estimation of the treatment effects. We calculated the propensity score to estimate the probability of each patient receiving intrathecal morphine by logistic regression. Our propensity score model included age, complex foot ankle surgery, insertional Achilles tendinopathy, BMI more than 30, and expected surgical time more than 2 hours. We matched the patient who received intrathecal morphine to the patients who received peripheral nerve blocks with a one-to-one ratio.
Participant Flow :	A total of 1093 anesthetic records of patients who underwent foot ankle surgery between January 2013 and December 2020 were screened and thoroughly reviewed. Foot ankle procedures included in this study are listed in Table 1. A total of 328 patients received either spinal anesthesia with 0.1 mg of intrathecal morphine (SBMO) or spinal anesthesia with US-guided peripheral nerve blocks (SBPNB): 273 and 55, respectively (Fig.1).
Adverse events :	none
Outcome Measures :	1.Primary endpoint was the proportion of patients who required rescue analgesic medication during the first postoperative 24 hours. 2.Secondary outcomes were mean pain scores in patients at the 6th, 12th, and 24th hours after surgery, side effects from peripheral nerve blocks such as ecchymosis, persistent numbness, and neuropathic pain related to nerve injury from peripheral nerve blocks, and side effects of intrathecal morphine including respiratory depression, nausea vomiting, pruritus, and urinary retention required catheterization.
Brief Summary of Results :	Proportion of patients who required rescue analgesic in SBMO group was significantly lower than SBPNB. (aHR 0.26 with 95% CI: 0.09,0.72), p value 0.010) (Fig.2).

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