

**TCTR ID : TCTR20150921002**

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

**OTHER ID :**

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

---

**Tracking Information**

First Submitted Date : 18 September 2015  
First Posted Date : 21 September 2015  
Last Update Posted Date : 25 July 2021

---

**Title**

Public Title : Efficacy of ultrasound guided rectus sheath block to improve post-operative pain control in day case laparoscopic tubal ligation  
Acronym : No Data  
Scientific Title : Efficacy of ultrasound guided rectus sheath block to improve post-operative pain control in day case laparoscopic tubal ligation  
Sponsor ID/ IRB ID/ EC ID : 58-155-08-1  
Registration Site : Thai Clinical Trials Registry  
URL : <https://www.thaiclinicaltrials.org/show/TCTR20150921002>  
Secondary ID : No Secondary ID

---

**Ethics Review**

1. Board Approval : Submitted, approved  
Approval Number : 58-155-08-1  
Date of Approval : 02 September 2015  
Board Name : the office of human research ethics committee  
Board Affiliation : HREC  
Board Contact : Business Phone : 074451149 Ext. No Data  
Business Email : medpsu.ec@gmail.com  
Business Address : 15 Karnjanavanich Road, Hat Yai, Songkhla

---

**Sponsor**

Source(s) of Monetary or Material Supports : Faculty of medicine PSU  
Study Primary Sponsor : Faculty of medicine PSU  
Responsible Party : Name/Official Title : faculty of medicine  
Organization : Prince of songkla university  
Phone : 074451157 Ext. No Data  
Email : medpsu.ec@gmail.com  
Study Secondary Sponsor : Department of anesthesiology PSU

---

**Protocol Synopsis**

Protocol Synopsis : We hope that rectus sheath block will improve post-operative pain score in day case laparoscopic tubal ligation comparison with multimodal analgesia only and decrease the time that patient stay in PACU, decrease rate of admission due to pain or other adverse effect from analgesic drug. After generalize anesthesia with oroendotracheal tube was performed all of the patient will receive Ketorolac intravenously after that the patient in control group will go on surgery as usual but in rectus sheath block group, patient will receive bilateral rectus sheath block with 0.25% bupivacaine 10ml each site. At the recovery room all patients will receive Acetaminophen 15-20 mg/kg orally and the pain score was recorded at 0, 1, 6, 24 hr post operative period

---

**URL not available**

---

**Health Conditions**

Health Condition(s) or Problem(s) Studied : post operative pain in laparoscopic tubal ligation resulted in more narcotic use and increase rate of admission in day case surgery.  
Keywords : post operative pain in laparoscopic tubal ligation

---

## Eligibility

Inclusion Criteria : patient who was scheduled for laparoscopic tubal ligation under generalized anesthesia  
 Gender : Female  
 Age Limit : Minimum : N/A (No limit) Maximum : N/A (No limit)  
 Exclusion Criteria : -history of allergy to Propofol, Cisatracurium, Fentanyl, Bupivacaine, Ondansetron, Ketorolac, Neostigmine, Atropine, Acetaminophen  
 -history of chronic pain  
 -history of gastroesophageal reflux disease  
 -other procedure in this operation  
 Accept Healthy Volunteers : Yes

## Status

Overall Recruitment Status : Completed  
 Key Trial Dates Study Start Date (First enrollment) : 18 September 2015 Indicate Type : Actual  
 Completion Date (Last subject, Last visit) : 18 January 2019 Indicate Type : Actual  
 Study Completion Date : 21 January 2019 Indicate Type : Actual

## Design

Study Type : Interventional  
 Primary Purpose : Treatment  
 Study Phase :  
 Intervention Model : Parallel  
 Number of Arms : 2  
 Masking : Masked Masked Role : Subject, Outcome Assessor,  
 Allocation : Randomized  
 Control : No treatment / Standard of care  
 Study Endpoint Classification : Efficacy Study  
 Sample size  
 Planned sample size : 66  
 Actual sample size at study completion : 66  
 Intervention Arm 1  
 Intervention name : Not done intervention(multimodal analgesia only)  
 Intervention Type : Experimental  
 Intervention Classification : Procedure/Surgery  
 Intervention Description : after induction of anesthesia, Ketorolac was given intravenously. At the recovery room patient was given acetaminophen orally  
 Intervention Arm 2  
 Intervention name : Bilateral rectus sheath block plus multimodal analgesia  
 Intervention Type : Experimental  
 Intervention Classification : Procedure/Surgery  
 Intervention Description : injection of 0.25% bupivacaine 10ml per site at below rectus muscle bilaterally

## Outcome

### Primary Outcome

1. Outcome Name : post-op analgesia requirement  
 Metric / Method of measurement : analgesic dose  
 Time point : 1 hr, 6 hr, 24hr

### Secondary Outcome

1. Outcome Name : time to discharge from recovery room  
 Metric / Method of measurement : calculate the time in recovery room  
 Time point : after extubation and transfer to recovery room  
 2. Outcome Name : pain score

Metric / Method of measurement : VNRS

Time point : 1, hr, 6 hr, 24 hr

3. Outcome Name : time to first dose of analgesia at home

Metric / Method of measurement : calculate time from discharge to first dose of analgesia at home

Time point : hour

---

## Location

### Section A : Central Contact

|                        |                       |                                   |                                |
|------------------------|-----------------------|-----------------------------------|--------------------------------|
| Central Contact        | First Name : Jinsupha | Middle Name :                     | Last Name : Aphinyankul        |
|                        | Degree :              | Phone : 0876839800 Ext. : No Data | Email : miffy_mook@hotmail.com |
| Central Contact Backup | First Name : Sirikarn | Middle Name :                     | Lastname : Siripruekpong       |
|                        | Degree :              | Phone : 0869693308 Ext. : No Data | Email : sirijane@hotmail.com   |

### Section B Facility Information and Contact

1. Site Name : Prince of songkla university

City : No Data State/Province : Songkla Postal Code : 90110

Country : Thailand Recruitment Status : Recruiting

|                  |                       |                                     |                                |
|------------------|-----------------------|-------------------------------------|--------------------------------|
| Facility Contact | First Name : Jinsupha | Middle Name :                       | Last Name : Aphinyankul        |
|                  | Degree :              | Phone : 08-7683-9800 Ext. : No Data | Email : miffy_mook@hotmail.com |

|                         |                       |                                     |                              |
|-------------------------|-----------------------|-------------------------------------|------------------------------|
| Facility Contact Backup | First Name : Sirikarn | Middle Name :                       | Last Name : Siripruekpong    |
|                         | Degree :              | Phone : 08-6969-3308 Ext. : No Data | Email : sirijane@hotmail.com |

|                   |                       |                              |                         |
|-------------------|-----------------------|------------------------------|-------------------------|
| Investigator Name | First Name : Jinsupha | Middle Name :                | Last Name : Aphinyankul |
|                   | Degree :              | Role : Site Sub-Investigator |                         |

### Section C : Contact for Public Queries (Responsible Person)

|                       |                                   |                                |
|-----------------------|-----------------------------------|--------------------------------|
| First Name : Jinsupha | Middle Name :                     | Last Name : Aphinyankul        |
| Degree : No Data      | Phone : 0876839800 Ext. : No Data | Email : miffy_mook@hotmail.com |

Postal Address : department of anesthesiology Prince of songkla university 15 Karnjanavanich Rd., Hat Yai

State/Province : Songkla Postal Code : 90110

Country : Thailand Official Role : Study Principal Investigator

Organization Affiliation : principal investigator

### Section D : Contact for Scientific Queries (Responsible Person)

|                       |                                   |                              |
|-----------------------|-----------------------------------|------------------------------|
| First Name : Sirikarn | Middle Name :                     | Last Name : Siripruekpong    |
| Degree : MD           | Phone : 0869693308 Ext. : No Data | Email : sirijane@hotmail.com |

Postal Address : 15 Karnjanavanich Road

State/Province : Songkhla Postal Code : 90110

Country : Thailand Official Role : Study Principal Investigator

Organization Affiliation : Faculty of Medicine, Prince of Songkla 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