

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 general 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, Ketolorac 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
