TCTR ID : TCTR20150921002

OTHER ID :

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

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 laparoscopoic tubal ligation comparision 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 drugAfter generalize anesthesia with oroendothechial tube was perform 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 nacrotic use and increase rate of admission in day case surgery.
Keywords :	post operative pain in laparoscopic tubal ligation

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Eligibility

Inclusion Criteria :	patient who was schedual 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 gatroesophageal 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
Intervantion 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
Intervantion 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 adn 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

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