ISRCTN18151624 https://doi.org/10.1186/ISRCTN18151624

Double-sided back muscle numbing for pain relief pain after having the gallbladder removed using keyhole surgery

Submission date
16/09/2023

Recruitment status
No longer recruiting

Registration date
21/09/2023

Overall study status
Completed

Last Edited
21/09/2023

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Laparoscopic cholecystectomy is a specific type of surgery where the gallbladder is removed using small incisions and a camera. An erector spinae block is a medical procedure in which a local anesthetic (a medication that numbs sensation) is injected near the erector spinae muscles along the spine. This is done to block or numb the nerves that transmit pain signals from the surgical area to the brain. The purpose of using this block is to provide effective pain relief during and after the surgery. By numbing the nerves in the area, it helps reduce the amount of pain the patient feels, making the surgical procedure more comfortable and improving the postoperative recovery experience. It's a part of the overall pain management strategy for the surgery, potentially leading to better pain control and a smoother recovery process for the patient.

Who can participate?
Patients getting laparoscopic cholecystectomy

What does the study involve?
Patients were split into two groups: one receiving general anesthesia plus regular pain control, and the other receiving both of those plus an erector spinae block.

What are the possible benefits and risks of participating?
The potential advantages include better pain relief, while the risks involve the use of ultrasound to guide the block.

Where is the study run from?
Universidad del Sinu (Colombia)

When is the study starting and how long is it expected to run for?
May 2021 to February 2023

Who is funding the study?
Universidad del Sinu (Colombia)

Who is the main contact?
Mauro Causil, jjmoralesb@unal.edu.co

Contact information

Type(s)
Principal investigator

Contact name
Mr Mauro Causil

Contact details
CALLE 38
52 249 LOS ALPES
Sincelejo
Colombia
70001
+57 3188762847
jjmoralesb@unal.edu.co

Additional identifiers

Protocol serial number
08012021

Study information

Scientific Title
Bilateral erector spinae block for postoperative analgesia in laparoscopic cholecystectomy: A randomized clinical trial

Study objectives
ESPB improves postoperative analgesia and reduces opioid consumption

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/01/2021, Clinica La Concepcion Ethics Comittee (CALLE 38 52 249 LOS ALPES, Sincelejo, 700001, Colombia; (+57) 5 2749180; info@laconcepcion.org), ref: 08012021

Primary study design
Interventional

Study design
Prospective interventional randomized clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Improvement of analgesia in patients undergoing laparoscopic cholecystectomy

Interventions
There were 2 study arms: one was general anaesthesia + standard analgesia and the other arm was general anaesthesia + standard analgesia + bilateral US-guided erector spinae block.Follow up was 48 hrs after surgery to record pain scores. The randomization process was done using Epi Dat 4.2.

Intervention Type
Other

Primary outcome(s)
Pain measured using a 0 (least)-10 (worst) pain score 1, 6, 12, 24 and 48 hr after surgery

Key secondary outcome(s)
Requirement of opioid (Yes or No) 1 hour after surgery

Completion date
28/02/2023

Eligibility

Key inclusion criteria
1. More than 18 years old
2. ASA I,II
3. Undergoing laparoscopic cholecystectomy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment

Key exclusion criteria
1. IMC >30
2. Open cholecystectomy
3. Allergy to local anesthetics
4. Recent opioid use

Date of first enrolment
01/08/2021

Date of final enrolment
28/02/2023

Locations

Countries of recruitment
Colombia

Study participating centre
Clinica La Concepcion
CALLE 38 52 249 LOS ALPES
Sincelejo
Colombia
700001

Sponsor information

Organisation
Universidad del Sinú

ROR
https://ror.org/013ys5k90

Funder(s)

Funder type
University/education

Funder Name
Universidad del Sinú

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and or analyses during the current study will be available upon request from jjmoralesb@unal.edu.co

IPD sharing plan summary
Available on request