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Evaluating a new surgical method for reducing pain after ventral hernia repair

Submission date
17/10/2024

Recruitment status
No longer recruiting

Registration date
21/10/2024

Overall study status
Completed

Last Edited
21/10/2024

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
Ventral hernia, often linked with a condition called diastasis rectus abdominis, is a common issue in general surgery. The e-TEP technique is a promising method for fixing this problem, but it can cause significant pain after surgery. This study aims to test a new pain relief method and compare it to existing ones to see which works best.

Who can participate?
Adults aged between 18 and 65 years old who have a ventral hernia associated with diastasis rectus abdominis can participate in this study.

What does the study involve?
Participants will undergo surgery using the e-TEP technique to correct their hernia. They will be randomly assigned to one of three pain relief methods: general anesthesia alone, general anesthesia with an ultrasound-guided TAP block, or general anesthesia with a TAP block guided by direct laparoscopic view. Pain levels will be measured at 2, 6, and 24 hours after surgery.

What are the possible benefits and risks of participating?
The potential benefit is finding a more effective way to manage pain after hernia surgery. However, there are risks associated with surgery and anesthesia, including pain, complications, and the usual risks of surgical procedures.

Where is the study run from?
The study is being conducted at Gafrée e Guinle University Hospital (Brazil)

When is the study starting and how long is it expected to run for?
February 2023 to March 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Daniel Mariano de Andrade at danielmarianodeandrade@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
UTN is U1111-1314-6764

Study information

Scientific Title
E-TEP surgery for ventral hernias: a novel and effective approach to postoperative analgesia

Study objectives
Compare the effectiveness of direct visualization TAP block to ultra-sound guided TAP block and general anesthesia alone for pain control after ventral hernia and diastasis rectus abdominis correction surgery using laparoscopic e-TEP, as well as their administration times.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 28/02/2023, Research Ethics Committee of the Gaffréé e Guinle University Hospital (Mariz e Barros Street, n 775 - Maracanã, Rio de Janeiro, 20270-004, Brazil; +55 (21)97246-8917; cep.hugg@unirio.br), ref: Version 2; CAAE: 66449322.4.0000.5258; Project Approval Number: 5.915.842

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Study of the effectiveness provided by Direct Visualization TAP Block analgesia in patients submitted to Diastasis Rectus Abdominis (DRA) associated with Ventral Hernia (VH) correction surgery.

Interventions
A total of 30 patients, aged between 18 and 65 years, were selected to undergo surgery to correct Diastasis Rectus Abdominis associated Ventral Hernia using the laparoscopic e-TEP technique. The patients were randomly divided into three groups based on the analgesia protocol: direct visualization TAP Block, ultrasound-guided TAP Block, and general anesthesia alone. The randomization technique used was alternate allocation, ensuring an equal number of patients in each group.

The duration of the treatment was the time spent in performing the surgeries (156 - 218 minutes on average per surgery) and Local Anesthetic administration (1 minute and 53 seconds on average), since it was an on time intervention.

The follow-up of the 3 arms studied was 1 year in duration.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Postoperative pain was assessed at 2h, 6h and 24h post-surgery, by direct verbal questioning, using the numeric rating scale, from 0 (no pain) to 10 (worst imaginable pain)

Key secondary outcome(s))
Local anesthetic administration time was also ascertained at 2h, 6h and 24h post-surgery, comparing the GA, US-TAPB and DV-TAPB groups

Completion date
17/03/2024

Eligibility

Key inclusion criteria
Patients, aged between 18 and 65 years old, who presented with Ventral Hernia associated with Diastasis Rectus Abdominis.

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
30

Key exclusion criteria
1. Age <18 or >65 years
2. Allergy to local anesthetic
3. History of chronic pain
4. Continuous use of analgesics and corticosteroids
5. Presence of sensory peripheral neuropathies
6. Glycated hemoglobin >6.5%
7. Body mass index (BMI) >40 kg/m²
8. Hernia and/or diastasis >8 cm
9. Surgical risk ASA >II
10. Patients who required Transversus Abdominis Release (TAR) during surgery were also excluded

Date of first enrolment
28/02/2023

Date of final enrolment
31/10/2023

Locations

Countries of recruitment
Brazil

Study participating centre
Gafrée e Guinle University Hospital - HUGG - UNIRIO
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Sponsor information

Organisation
Gafrée e Guinle University Hospital

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be available upon request from Daniel Mariano de Andrade (main author)
danielmarianodeandrade@gmail.com

IPD sharing plan summary
Available on request