

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

Submission date 17/10/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/10/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 21/10/2024	Condition category Surgery	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

Contact name

Dr Daniel Mariano de Andrade

ORCID ID

<http://orcid.org/0009-0007-9779-3404>

Contact details

Mariz e Barros Street, n 775 - Maracanã
Rio de Janeiro
Brazil
20270-004
+55 (21)98272-8272
daniel.andrade@ebserh.gov.br

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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 Gaffrée 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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

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 measure

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)

Secondary outcome measures

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

Overall study start date

28/02/2023

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

30

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

Mariz e Barros Street, n 775

Rio de Janeiro

Brazil

20270-004

Sponsor information

Organisation

Gafrée e Guinle University Hospital

Sponsor details

Mariz e Barros Street, n 775 - Maracanã

Rio de Janeiro

Brazil

22210-085

+55 (21)982728272

cep.hugg@unirio.br

Sponsor type

Hospital/treatment centre

Website

<https://www.gov.br/ebserh/pt-br/hospitais-universitarios/regiao-sudeste/hugg-unirio>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

15/11/2024

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