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Pain relief for children who are undergoing hernia surgeries, using a landmark technique or using ultrasound guidance

Submission date
02/09/2022

Recruitment status
No longer recruiting

Registration date
16/09/2022

Overall study status
Completed

Last Edited
29/12/2023

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Caudal epidural block is a popular regional anaesthetic technique in children undergoing infraumbilical surgeries (surgery below the navel). The aim of this study is to compare overall block success rates between the conventional and ultrasound-guided methods of caudal blocks. Other objectives are to compare block performance time and the number of attempts when using the two techniques.

Who can participate?
Children aged 1-8 years belonging to ASA physical status grades 1 and 2, undergoing elective inguinal hernial surgeries under general anaesthesia with caudal blocks.

What does the study involve?
Participants were divided into two groups and underwent caudal blocks either by the conventional landmark technique, or by the ultrasound-guided method. The child is given general anaesthesia as per standard practice and then given the caudal block for analgesia.

What are the possible benefits and risks of participating?
Participating in the study would ensure that the child will be pain-free during the surgery and postoperatively. As it is a commonly done procedure for pain relief, risks would include the usual risks involved in the caudal procedure. There is no higher than normal risk if participating in this study.

Where is the study run from?
St John's Medical College and Hospital (India)

When is the study starting and how long is it expected to run for?
October 2019 to September 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Mythreyi Muthu Krishnan, mythu.apr24@gmail.com
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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IEC/1/942/2019

Study information

Scientific Title
Ultrasound-guided versus conventional caudal block in children

Acronym
USG-C

Study objectives
The success rate of ultrasound-guided caudal block is superior to the conventional landmark technique

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/10/2019, Institutional Ethics Committee (St John's Medical College and Hospital, Sarjapur road, Bangalore 560034, India; +91 80-49466346; sjmc.ierb@stjohns.in), ref: 292/2019

Study design
Single centre interventional randomized control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
https://docs.google.com/document/d/1AOqTmaU7D3Lptav47pd09cStvf2QkKw2/edit?usp=sharing&ouid=107381355958173307208&rtpof=true&sd=true

Health condition(s) or problem(s) studied
Intraoperative and postoperative analgesia among children undergoing elective inguinal hernia surgeries

Interventions
Sixty-four children aged 1-8 years belonging to ASA physical status groups 1 and 2 undergoing elective inguinal hernial surgery were studied. After induction of general anaesthesia, they were administered caudal blocks depending on the groups they were randomly allocated to using a computer-generated lot system:
Group A (conventional) – 0.5 ml/kg of 0.25% Bupivacaine was injected after the needle entered

the sacral canal
Group B (USG) – 0.5 ml/kg of 0.25% Bupivacaine was injected right after the needle was visualised piercing the sacrococcygeal ligament in the longitudinal view.

The children were monitored during surgery every 5 minutes for adequacy of analgesia. There was hemodynamic and respiratory monitoring in the Post Anesthesia Care Unit (as is customary for all general anaesthesia).

Intervention Type
Procedure/Surgery

Primary outcome measure
Overall block success rate, defined as the absence of significant motor movements at the time of surgical incision, or a significant increase in heart rate (HR)/respiratory rate (RR)

Secondary outcome measures
1. Block performance time, calculated as the time period from identification of structures to the termination of injection of local anaesthetic
2. Number of attempts taken: if the patient is pricked with a needle and it is then removed, it is considered an attempt. The maximum number of attempts was three, the third attempt being made by another senior anaesthesiologist.

Overall study start date
15/10/2019

Completion date
30/09/2021

Eligibility

Key inclusion criteria
1. Between 1-8 years of age with no contraindications for caudal block
2. Scheduled for elective inguinal hernia surgeries
3. Belonging to ASA physical status 1 or 2

Participant type(s)
Patient

Age group
Child

Lower age limit
1 Years

Upper age limit
8 Years

Sex
Both

Target number of participants
64

Total final enrolment
64

Key exclusion criteria
1. Consent not given for the procedure
2. Contraindications for caudal block

Date of first enrolment
01/11/2019

Date of final enrolment
01/09/2021

Locations

Countries of recruitment
India

Study participating centre
St. John's Medical College and Hospital
Sarjapur road
Bangalore
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Sponsor information

Organisation
St. John's National Academy of Health Sciences

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Sponsor type
Hospital/treatment centre

Website

http://www.stjohns.in/

ROR
https://ror.org/03qvjzj64

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
30/09/2022

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			14/09/2022	No	Yes
Results article		01/08/2023	29/12/2023	Yes	No