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Lateral upper thigh approach to sciatic and femoral nerve blocks in children

Submission date
18/09/2017

Recruitment status
No longer recruiting

Registration date
20/09/2017

Overall study status
Completed

Last Edited
10/07/2018

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Regional anesthesia is the use of local anesthetics to block sensations of pain from a large area of the body, such as the leg. Regional anesthesia of the leg usually consists of injections of local anesthetic close to two nerves called the sciatic and femoral. Normally this technique involves two needle punctures at different sites, one in the groin area, and one in the buttock, including the need to reposition the patient. The aim of this study is to investigate the feasibility of a new technique of blocking both nerves from the single injection site located at the upper thigh without repositioning the patient.

Who can participate?
Children aged 5-18 undergoing lower limb surgery below the middle of the thigh

What does the study involve?
All participants receive sciatic and femoral nerve blocks according to the new technique in the operating theatre. The possibility of blocking both nerves from one injection site is checked. The mean distances from skin to nerves are measured. After surgery pain intensity is assessed after 1, 3, 6, 12 and 24 hours.

What are the possible benefits and risks of participating?
Patients undergo thorough monitoring of their pain after surgery and receive rescue analgesic (painkiller) drugs as soon as they are needed. The risks of participating in the study include hematoma (bruise) formation due to unintentional puncture of blood vessels in the region of the block.

Where is the study run from?
Lviv Regional Childrens' Clinic Hospital (Ukraine)

When is the study starting and how long is it expected to run for?
January 2017 to April 2017

Who is funding the study?
Lviv Regional Childrens' Clinic Hospital (Ukraine)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
3-14-12-16

Study information

Scientific Title
Lateral supratrochanteric approach to sciatic and femoral nerve blocks in children: a feasibility study

Study objectives
Femoral and sciatic nerves can be blocked from the single needle insertion point located at the junction of lower and middle third of distance between the greater trochanter and iliac crest along the mid-axillary line.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Lviv Regional Children's Hospital Ethics Committee, 14/12/2016, Protocol #3

Study design
Interventional open label non-randomized single centre 4-month feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Lower extremity surgery

Interventions
Single shot neurostimulator-guided sciatic and femoral nerve blocks with bupivacaine 0.25% 0.3 ml/kg and 0.3 ml/kg respectively.

All participants received sciatic and femoral neve blocks in the operating theatre. The possibility of blocking two nerves (eliciting of motor response) from one injection site was checked. Mean distances from skin to nerves were registered. After surgery pain intensity was assessed after 1, 3, 6, 12 and 24 hours.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. The possibility of single injection site sciatic and femoral nerve blocks:
1.1. The possibility to perform sciatic nerve block from supratrochanteric area along mid-axillary line was assessed once at the moment of performing the block and was defined as possibility of eliciting motor response (plantar flexion) on neurostimulation with following neurostimulator settings: current 0.4 mA, impulse duration 0.3 ms and impulse frequency 2 Hz
1.2. The possibility to perform femoral nerve block from the same point also was assessed once at the moment of performing the block and was defined as possibility of eliciting motor response (patellar twitches) on neurostimulation with the same settings

Secondary outcome measures
1. Skin to nerve distances assessed once at the moment of performing the blocks using insulated needles with centimeter markings (Stimuplex A, 21G, 150 mm, B.Braun, Melsungen, Germany).

The depth of needle insertion equaled to skin-to-corresponding nerve distance.
2. Pain intensity assessed according to Numeric Rating Scale (NRS, 0-10 points) during the first postoperative day at 1, 3, 6, 12 and 24 postoperative hours

Overall study start date
01/01/2017

Completion date
30/04/2017

Eligibility

Key inclusion criteria
1. 5-18 year old children of both genders undergoing lower limb surgery below middle of thigh
2. ASA status 1 or 2
3. Parental written informed consent for SNB, FNB and study participation

Participant type(s)
Patient

Age group
Child

Lower age limit
5 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Anatomical abnormality in block region
2. Contraindications to regional anesthesia

Date of first enrolment
09/01/2017

Date of final enrolment
11/04/2017

Locations

Countries of recruitment
Ukraine

Study participating centre
Lviv Regional Childrens' Clinic Hospital
Lysenka 31
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

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Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Lviv Regional Childrens' Clinic Hospital

Results and Publications

Publication and dissemination plan
Study protocol is not published and is not available online. Study protocol and statistical analysis are stored on investigators’ personal computers and are available upon request (a. albokrinov@gmail.com). The manuscript has been reviewed and will be published in 2017.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
Patients' data sheets are stored at the repository of Lviv regional Childrens' Clinic Hospital and are available upon request. These data sheets can be obtained immediately after written request approval by hospital authority. Statistical analysis is stored on personal computers of the investigators and can be provided upon request (a.albokrinov@gmail.com). Written informed parental consent was obtained in all cases and additional patients' consents were obtained in case if patient was 14 or more years old. Patients were anonymized by registering only initials and patients' numbers in data sheets.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2017		Yes	No