

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

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
18/09/2017	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
20/09/2017	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
10/07/2018	Surgery	

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?

Dr Andrew Albokrinov

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

3-14-12-16

Study information

Scientific Title

Lateral supr trochanteric 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

Study type(s)

Treatment

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 nerve 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(s)

1. The possibility of single injection site sciatic and femoral nerve blocks:
 - 1.1. The possibility to perform sciatic nerve block from suprtrochanteric 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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

5 years

Upper age limit

18 years

Sex

All

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

Lviv

Ukraine

79008

Sponsor information

Organisation

Lviv Regional Childrens' Clinic Hospital

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Lviv Regional Childrens' Clinic Hospital

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes