

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

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

## **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 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

## **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?
<a href="#">Results article</a>	results	01/11/2017		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes