

# CLONidine and ROPivacaine in peripheral nerve blocks in children

<b>Submission date</b> 28/02/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 15/03/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/01/2020	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## Study information

**Scientific Title**

Sciatic lateral popliteal block with clonidine alone or clonidine plus 0.2% ropivacaine: effect on the intra- and postoperative analgesia for lower extremity surgery in children, a randomised prospective controlled study

**Acronym**

CLON, ROP

**Study objectives**

Our hypothesis was that clonidine alone or combined with 0.2% ropivacaine could produce a long lasting sciatic lateral popliteal block (SLPB) after foot and ankle surgery, adequate for the first postoperative day.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Scientific Ethics Committee of General Children's Hospital, Penteli, Athens approved on 20/05 /2008

**Study design**

Single-centre interventional prospective randomised controlled study

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

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

**Health condition(s) or problem(s) studied**

Disturbances of Achilles tendon and club foot

**Interventions**

Between January 2009 to May 2010, 77 consecutive children, American Society of Anesthesiologists (ASA) physical status I and II, aged 5-14 years were scheduled for elective mild to moderate painful foot and ankle surgery.

66 children were randomly assigned to three groups by means of a computer generated table to receive either isotonic saline (n=21) or clonidine (n =23) or clonidine plus 0.2% ropivacaine (n=22), during performance of a sciatic lateral popliteal block (SLPB) plus femoral block. The investigators were blind to the group assignment. The placebo or the treatment solutions were prepared by the pharmacy and supplied to the Department of Anaesthesia in syringes labelled

with predetermined code for each solution. There were two syringes for the SLPB and the femoral block respectively.

In the SLPB, the syringes contained

1. For the control group isotonic saline 10 ml plus 0.25 ml/kg and saline 0.13 ml/kg
2. For the clonidine group isotonic saline 10 ml plus 0.25 ml/kg and clonidine 2 µg/kg (0.13 ml/kg) respectively
3. Finally in the clonidine plus 0.2% ropivacaine group the syringes contained 0.2% ropivacaine 10 ml plus 0.25 ml/kg (maximum 25 ml) and clonidine 2 µg/kg (0.13 ml/kg) respectively.

Similarly in the femoral block the syringes contained

1. For the control group isotonic saline: 0.4 ml/kg and 0.065 ml/kg respectively
2. For the clonidine group isotonic saline 0.4 ml/kg and clonidine 1 µg/kg (0.065 ml/kg) respectively
3. For clonidine plus 0.2% ropivacaine group 0.2% ropivacaine 0.4 ml/kg and clonidine 1 µg/kg (0.065 ml/kg) respectively. The maximum dose of 0.2% ropivacaine was decided to be 3.5 mg/kg and for clonidine 3 µg/kg.

In the anaesthetised children in the supine position, the SLPB was performed, using 100 mm or 50 mm, 21 gauge insulated stimulated needle. An additional femoral block became necessary for the use of tourniquet in the area around the thigh. After the performance of blocks a pneumatic tourniquet at 150 mmHg was applied to the mid-thigh.

Postoperative analgesia was assessed by means of a color analogue scale (CAS). Patients with mild or moderate postoperative pain (CAS score > 30 to 45 mm and 46 to 55 mm respectively) received nalbuphine 0.2 mg/kg and 0.3 mg/kg respectively.

## **Intervention Type**

Drug

## **Phase**

Not Applicable

## **Drug/device/biological/vaccine name(s)**

Clonidine, ropivacaine

## **Primary outcome measure**

Time to first analgesic request of nalbuphine after the surgery by Kaplan- Meier analysis. Postoperative analgesia was assessed by means of a colour analogue scale (CAS). Pain CAS score at rest, was assessed in the recovery room (0), 2, 4, 6, 8, 18, 24 hours postoperatively and the tourniquet pain (0). Total number of rescue nalbuphine doses and the total amount of nalbuphine for the 24 hours observational period.

## **Secondary outcome measures**

1. Classification of motor and sensory block
2. Restlessness based on dichotomous(yes or no)
3. Incidence of nausea and/or vomiting
4. Sedation level using a four-point scale
5. Childrens parents satisfaction score was assessed on the second postoperative day, using a numerical scale.

**Overall study start date**

01/01/2009

**Completion date**

31/05/2010

## Eligibility

**Key inclusion criteria**

1. Children who underwent Achilles lengthening
2. Children with club foot

**Participant type(s)**

Patient

**Age group**

Child

**Sex**

Both

**Target number of participants**

77

**Total final enrolment**

66

**Key exclusion criteria**

1. Children with neurologic or neuromuscular disease or problems in communication
2. Childrens parents refusal
3. Skin infection at the site of needle insertion

**Date of first enrolment**

01/01/2009

**Date of final enrolment**

31/05/2010

## Locations

**Countries of recruitment**

Greece

**Study participating centre**

8 V. Mela str

Holargos, Athens

Greece

15561

# Sponsor information

## Organisation

The Pharmacy Department of General Children's Hospital (Greece)

## Sponsor details

8 Hippocratous str  
P.Penteli, Athens  
Greece  
15236

## Sponsor type

Hospital/treatment centre

## ROR

<https://ror.org/05xt49662>

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

Department of Anesthesiology & the Pharmacy Department of General Children's Hospital (Greece)

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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[Results article](#)

results

01/02/2012

24/01/2020

Yes

No