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CLONidine and ROPivacaine in peripheral nerve blocks in children

Submission date	Recruitment status	[ ] Prospectively registered
28/02/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
15/03/2011	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/01/2020	Musculoskeletal Diseases	

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 1µg/kg (0.065 ml/kg) respectively
3. For clonidine plus 0.2% ropivacaine group 0.2% ropivacaine 0.4 ml/kg and clonidine 1µg/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 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
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Sponsor information

Organisation
The Pharmacy Department of General Children's Hospital (Greeece)

Sponsor details
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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?

Results article	results	01/02/2012	24/01/2020	Yes	No