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IV Steroids Versus Steroids Included in Block for Orthopedic Lower Limb Surgery

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Introduction:

IV and included steroids have produced the same length of block prolongation in adults as if the steroid was given with the nerve block. Clinically, we have not noticed this in children. The objective of this study is to examine this in young patients. We will blindly give the steroid either in the IV or in the block solution (perineural). This is a prospective double blind study.

Inclusion:

- Male and female subject's ages 5 – 25 years of age
- Scheduled for lower limb orthopedic procedures
- ASA class I - III

Groups:

- Steroids in the IV group 25 – 50
- Steroids in block group 25 – 50

Subjects will be randomized to either group; the syringes will be mixed by the pharmacy and blinded to the study personnel.

Methods:

Subjects will be anesthetized as standard of care, once anesthetized and IV catheters are placed, subjects will be given 0.1 – 0.15 mg/kg dexamethasone or placebo IV, nerve block will be administered perineural with, Mepivacaine with epinephrine 0.25%, 4.0 mg/kg plus 0.1 – 0.15 mg/kg dexamethasone or placebo.

Syringe Options Randomized:

1. Steroids given Intravenously
 - 20 cc - Nerve block solution, Mepivacaine with epinephrine 0.25% (4.0 mg/kg) + placebo.
 - 5 cc - steroids given IV (0.1 – 0.15 mg/kg)
2. Steroids given in nerve block solution
 - 20 cc - local (4.0 mg/kg) + steroids (0.1 – 0.15 mg/kg)
 - 5 cc - Placebo IV

We will record the time of block, IV injection and the surgery time and medications given in recovery. A phone call will be made to the patient or patient's parent at 24 hours and again at 48 hours if needed to ask how long they had pain relief.

STATISTICAL ANALYSIS PLAN:

Statistical analyses comparing the two groups were conducted with commercially available software (SigmaPlot 14, Systat Software, Inc., San Jose, CA, USA). Previous preliminary work with this treatment para STATISTICAL ANALYSIS PLANDigm demonstrated that $n \geq 23$ per group would be required to detect a significant difference in duration of analgesia with a statistical power of 0.8 with significance of $P < 0.05$. Categorical data were assessed with chi-squared analyses whereas continuous data were compared with unpaired, two-tailed Student's t-tests. Data were presented as raw values or mean \pm SD. $P < 0.05$ was considered significant.