

Pharmacological and Non-pharmacological Interventions in Management of Peripheral  
Venipuncture related Pain: A Randomized Clinical Trial

NCT04275336

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## **STUDY PROTOCOL**

### **Aim**

This study aims to examine the effectiveness of three different interventions including EMLA cream, distraction techniques and the integrating of EMLA cream and distraction techniques in managing venipuncture pain and stress of children.

### **Design**

A three-arm parallel, randomized controlled trial will be applied in this research. Eligible participants will be randomly assigned to into three groups: EMLA group, distraction group and combined group.

### **Interventions**

Hard copies of informed consent will give to all parents, while children's assent and eligibility data will be obtained from face-to-face interviews. Eligible children will be randomly assigned to into three groups: EMLA group, distraction group and combined group. Nurses will explain the pain rating scales, pharmacological and non-pharmacological techniques, and the usage of intravenous cannulation. Every child will be accompanied by a parent throughout the whole process. At baseline, patients' age, sex and ethnicity will be recorded before they are grouped.

The nurse who will perform venipuncture for children had 10 years of venipuncture experience in the pediatric ward. The intravenous cannula used is 19 gauge x 0.7-in. needle and the whole procedure adhere to standard IV cannulation procedures. While cannulation is ongoing, an

observer monitor the children and complete the revised-FLACC scale (r-FLACC). The observer, a senior pediatric nurse from the surgical department who had received pain assessment training, watch the procedure through real-time surveillance video. The HR and SpO<sub>2</sub> of children will also be recorded.

Transparent waterproof adhesive skin dressing will use to fix the cannulation. The children and parents will give their own Wong Baker and r-FLACC ratings as soon as the procedure is over. The sample of saliva will be take using the cortisol saliva ELISA assay kit for quantitative determination of salivary cortisol levels to evaluate children's stress during venipuncture. Any adverse effects resulted from the IV cannulation or EMLA cream will be observed and recorded during their entire hospitalization.

For the EMLA group , the specialist nurse who perform IV cannulation will determine the puncture site. A thick layer of EMLA cream (lidocaine and propiocaine 2.5%/2.5%) will be applied on a 1x1 cm<sup>2</sup> area of skin on the cannulation site. The transparent dressing will be covered on the cannulation site for 30 minutes, then remove it and clean the skin with a sterile cotton swab. Then nurse will perform IV cannulation for them.

For the distraction group , multiple distractions including toy whistles, cartoon books, TV showing cartoons, and various electronic products with video games will be provided for children to choose. They will be also taught breathing exercises (i.e. inhaling through the nose for 3 seconds and exhaling for 5 seconds, while they are counting) if they are willing. A play therapist play with the children for 5 minutes prior to and throughout the venipuncture procedure.

For the combined group , both EMLA cream and distraction techniques will be used. EMLA cream will be applied on the pre-puncture site for 30 minutes as the EMLA group, then the play therapist will encourage children to choose their favorite toys and play that with them 5 minutes before venipuncture or to do breathing exercises as the distraction group. During IV cannulation the play therapist will continue distracting the child with toys.

## STATISTICAL ANALYSIS PLAN

Statistical Package for Social Sciences (SPSS Inc., Chicago, IL, USA) for Windows (version 22.0) with statistical significance set to  $p < 0.05$ .

To answer the question that is there significant statistical difference in venipuncture pain score among lidocaine group, Attention diversion group and Combination group, Mann Whitney and Kruskal-Wallis will be used to compare the 2 and 3 groups respectively. The results will be present in a table in the form of median and interquartile range if the data is non-abnormal distribution. Otherwise, use mean $\pm$ standard deviation to describe the data.

To answer the question that is there significant statistical difference in children's salivary cortisol among lidocaine group, Attention diversion group and Combination group. Mann Whitney and Kruskal-Wallis will be used to compare the 2 and 3 groups respectively. The results will be present in a table in the form of median and interquartile range if the data is non-abnormal distribution. Otherwise, use mean $\pm$ standard deviation to describe the data.

To answer the question that is there significant statistical difference in children's HR, SpO<sub>2</sub> and venipuncture related findings like venipuncture times, venipuncture duration and indwelling needle duration of every child, Mann Whitney and Kruskal-Wallis will be used to compare the 2 and 3 groups respectively. The results will be present in a table in the form of median and interquartile range if the data is non-abnormal distribution. Otherwise, use mean $\pm$ standard deviation to describe the data.

To answer the question that what's the preference for toys of children in Attention diversion group and Combination group, frequency distribution percentage will be used. To answer the question that is there significant statistical difference of children's choice in toys between Attention diversion group and Combination group, the chi-square test will be used. All the data will be present in a table in the form of median and interquartile range if the data is non-abnormal distribution. Otherwise, use mean $\pm$ standard deviation to describe the data.