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

NCT04275336

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Inform consent form for children and their parents
CHILDREN'S HOSPITAL OF FUDAN UNIVERSITY

This inform consent form for the children and their parents who will be invited to participate in research, entitled "Pharmacological and Non-pharmacological Interventions in Management of Peripheral Venipuncture related Pain: A Randomized Clinical Trial**"**

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[Name of Organization] Children's Hospital of Fudan University

[Name of Sponsor] None

[Name of Proposal and version]: Pharmacological and Non-pharmacological Interventions in

Management of Peripheral Venipuncture related Pain: A Randomized Clinical Trial

This Informed Consent Form has two parts:

1.Information Sheet (to share information about the research with you)

2.Certificate of Consent (for signatures if you agree to take part)

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet
Introduction

- I am Yu Zhuowen, the head nurse of department of Pneumology and Gastroenterology. My team and I are doing research on pharmacological and non-pharmacological interventions in management of peripheral venipuncture related pain. I am going to give you information and invite you to be part of this research. Before you decide, you can talk to anyone you want to with about the research. When I introduce information, you can ask me what words you don't understand and I will explain them to you. If you have questions later, you also can ask the staff or me.

Purpose of the research

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 during venipuncture of children.

Type of research intervention

This research will involve three different interventions which will implement by nurse staff and/or game therapist during the intravenous cannulation. You and your child will be randomly assigned to 1) EMLA group where your child will be applied EMLA cream on the venipuncture site 30 minutes before the

intravenous cannulation, 2) distraction group where your children will engage in games for 5 minutes during intravenous cannulation, or 3) combined group where your child will be applied EMLA cream for 30 minutes then engage in the game for 5 minutes
before the intravenous cannulation.

Participant selection

I will invite children who will schedule to undergo the peripheral venipuncture during their hospitalization. The following inclusion criteria are for the children: 1) children aged 3 to 16 years; 2) Children who will receive their first peripheral intravenous puncture.

Voluntary participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will offer the treatment that is routinely offered in this ward, and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier.

Information on the Trial Drug [EMLA cream]

The drug we are testing in this research is called eutectic mixture of local anesthetics (EMLA) cream containing 25mg lidocaine and 25mg propiocaine per gram. It has been test before with people who have the peripheral venipuncture in reducing pain and stress. We are now want to combine it with distraction techniques and test whether they have effectiveness in reducing pain and stress in venipuncture in pediatric ward.

The EMLA cream is made by Beijing Zi Guang Pharmaceutical Co. Ltd. You should know that it has few side effect. This product can produce local reactions at the application site, which are more common in pallor, erythema (redness) and edema. These reactions are mostly transient and mild. Burning or itching sensation may also occur in the initial stage of use, but it is relatively rare.
Allergic reactions to amide local anesthetics (the most severe reaction is anaphylactic shock) are rare. High-dose prilocaine can cause the level of methemoglobin in the blood to increase.

One of three groups of this study will not be given the EMLA cream, instead, they will be distracted before and during the venipuncture using several toys (distractions) they choose.

Procedures and Protocol

Because we have no idea if the combined EMLA and distractions is better than single using of one of them. We need to compare the three. To do this, we will put people taking part in this research into three group. Eligible participants were randomly assigned on the three groups, via a computer- generated sequence.

For the EMLA group , the specialist nurse who is to perform IV cannulation determine the puncture site. A thick layer of cream (lidocaine and propiocaine 2.5%/2.5%) will be applied on a 1x1 cm2 area of skin on the cannulation site. The transparent dressing is leave in place for 30 minutes, then remove and clean with a sterile cotton swab. Then nurse perform IV cannulation for them.

For the distraction group, multiple distractions including toy whistles, cartoon books, a TV showing cartoons, and various electronic products with video games will be provided for the children to choose

and play with. 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 min. 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 5 minutes before the venipuncture, the play therapist will encourage them to choose their favorite toys to play with or to learn breathing exercises. During IV cannulation the play therapist also continue distracting the child with toys.

The healthcare workers will be looking after you and the other participants very carefully during the study. If there is anything you are concerned about or that is bothering you about the research please talk to me or one of the other researchers.

You and you children will ask to rate your child's pain during venipuncture using the different pain rating scales. And we will also take a little saliva of your child to get their salivary cortisol level to rate their stress. Additionally, your child's SpO2, heart rate during the intravenous cannulation will also be recorded.

Side effects
As already mentioned, the EMLA cream have some unwanted effects. . However, we will follow you closely and keep track of any unwanted effects or any problems. We may use some other medicines to decrease the symptoms of the side effects or reactions. Or we may stop the use of one or more drugs. If this is necessary we will discuss it together with you and you will always be consulted before we move to the next step.

Risk
By participating in this research it is possible that you will be at greater risk than you would otherwise be. For example, by using the the integrating of EMLA cream and distraction techniques, child's pain and stress become greater. you should be aware of the possibility. If something unexpected happens, we remedy it as possible as we can.

Benefits
If you participate in this research, you will have the following benefits: you will get a gift. Additionally, any interim illnesses will be treated at no charge to you. There may not many benefit for you but your participation is likely to help us find the answer to the research question. There may not be any benefit to help us find best method in management children's venipuncture pain and stress.

Confidentially
The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researcher will be able to see it. Any information about you will have a number on it instead of your name. When finish the study, all information about collected data will lock up in the special box and label it, and after keep it for two years then burning it in order to protect it confidentially about subjects' information.

Sharing the results
The knowledge that I get from this study will be shared with you before it is made widely available to the public. Confidential information will not be shared.

Right to Refuse or Withdraw

The participant does not have to agree to take part in this research if you do not wish to do so you may stop you from participating in the research at any time that you wish without you losing any of your rights.

Who to Contact
If you have any questions you may ask me now or later or you wish to ask questions later, you may contact me: Yu Zhuowen, Email: yzw100@126.com

PART II: Certificate of Consent
This section should be written in the first person and have a statement similar to the one in bold below. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. The certificate of consent should avoid statements that have "I understand…." phrases. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant_____
Signature of Participant _____
Date _____
Day/month/year

If illiterate
A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ AND Thumb print of participant
Signature of witness _____
Date _____
Day/month/year

Statement by the researcher/person taking consent
I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:
1.
2.
3.
I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____
Date _____
Day/month/year