Safety of Gebauer's Pain Ease and Gebauer's Ethyl Chloride

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STUDY TITLE: Study to determine the safety of ethyl chloride and pain ease sprays when used following chloraprep for invasive procedures

1) **STUDY AIM, BACKGROUND, AND DESIGN ABSTRACT**

This study aims to determine if application of Gebauer's Pain Ease or Gebauer's Ethyl Chloride numbing sprays will contaminate skin which has been prepped with chloraprep. Due to the recent national shortage of lidocaine we hope to be able to find a suitable alternative to lidocaine for topical analgesia during invasive procedures such as arterial lines and epidurals. Depending on the results of this study we will decide if it is safe to proceed to additional studies to determine if numbing sprays are effective alternatives to lidocaine for topical analgesia. Our plan is to compare the number of colony forming units (CFU) of bacteria that grow on a section of skin on the wrist and lower back prior to treatment, following chloraprep treatment, and following application of pain ease spray or ethyl chloride. Our hypothesis is that the sprays will not affect the sterility of the area and that there will not be a significant increase in bacterial growth after ethyl chloride or pain ease spray have been added to skin treated with chloraprep.

2) SUBJECT POPULATION AND ELIGIBILITY

We plan to ask for volunteers from Henry Ford employees. Our exclusion criteria will include people who have infections at the site or have a history of hypersensitivity to either the numbing sprays or chloraprep.

3) STUDY PROCEDURES

Our study will involve swabbing and culturing the skin of volunteers on the wrist where an arterial line is place, as well as on the lower back where an epidural is placed. First, a swab of the untreated area of wrist or lower back will be performed. Second, the section of skin will be treated with chloraprep according to standard procedure prior arterial line or epidural placement, and this treated skin will be swabbed. Third, the chloraprep-treated section of skin will be treated with numbing spray (either Gebaur's Ethyl Chloride or Pain Ease). For the Pain Ease group, the spray will be applied up to 10 seconds or until white appears (whichever comes first). If frosting appears, stop. The area that has been subsequently treated with chloraprep and numbing spray will then be swabbed. These swabs will be cultured by the HFHS microbiology lab on agar plates for 48 hours and the number of colony forming units (CFU) will be counted. The amount of bacterial growth will be compared between the untreated samples, chloraprep samples and the associated post-spray samples. Funding for the project will be from Gebauer, the manufacturer of the numbing sprays. Based on power analysis, for each spray, a sample size of 72 subjects with 6 swabs taken per subject (subsequent untreated, chloraprep, and numbing spray samples taken from the wrist and lower back from each subject) achieves 80 % power to detect an odds ratio of 24 using a two-sided McNemar test with a significance level of 0.05. The odds ratio is equivalent to a difference between two paired proportions of 0.115 which occurs when the proportion in cell 1,2 is 0.12 and the proportion in cell 2,1 is 0.005. The proportion of discordant pairs is 0.125. As there are two separate sprays being investigated independently, the final number of subjects will be 144, with 6 swabs taken per subject.

Data Analysis and Statistical Considerations

We will collect data on an excel spreadsheet. We will not collect any personal health information or identifying information for the participants.

4) ANTICIPATED RISKS

There are no likely risks to participants in this study. Less likely risks include hypersensitivity to the products, risk of frostbite, risk of skin pigment alteration, and Ethyl Chloride is a flammable substance. We will decrease the risk of frostbite by limiting exposure to the numbing sprays to the initial formation of crystals on the skin.

5) **ANTICIPATED BENEFITS**

There are no anticipated benefits to the participants however we hope that this study will allow us to perform additional trials which may benefit others.

6) RENUMERATION/COMPENSATION

There will be no compensation offered to participants.

7) COSTS

The only costs associated with this project will be the materials used. The manufacturer of pain ease and ethyl chlorides sprays will cover the costs of these products.

8) ALTERNATIVES

There are no alternatives

9) CONSENT PROCESS AND DOCUMENTATION

Consent of volunteers will be obtained by one of the investigators prior to participation in the study. Participants will be given written consent and offered the opportunity to ask any questions they may have prior to participation in the study. Consent forms will be signed and stored in the primary investigators locked office.

10) WITHDRAWAL OF SUBJECTS

There are no anticipated circumstances under which subjects will be withdrawn from research without their consent.

11) PRIVACY AND CONFIDENTIALITY

No personal identifiers will be kept or obtained for participants in the study. We will not be accessing the health records of patients.

12) DATA AND SAFETY MONITORING PLAN

Data quality will be maintained by the primary investigator as well as the co-investigators.

13) QUALIFICATIONS OF THE INVESTIGATOR(S)

Dr. Attali is the head of the obstetrical anesthesia department and has done many studies to improve patient care.