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Protocol

Effects of LI.4 acupressure and cold application on behavioural responses to pain and physiological parameters among infants receiving intramuscular injection: a randomized controlled trial protocol

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ABSTRACT

Background: Vaccination protects children from many diseases. However, it often causes anxiety and distress for them despite its benefits. This trial aims to assess the effect of acupressure (Li.4) and cold application on pain and physiological parameters in children getting intramuscular injections.
Methods: The study is designed as a randomized controlled trial with a crossover approach. Participants who meet the inclusion criteria will be randomly divided equally into two groups. Group I (85) and Group II (85). Using Sequentially Numbered Opaque Sealed Envelops (SNOSE), each infant will act as their own matched control. In the first sequence, group I will receive acupressure, and group 2 will receive cold application. In sequence 2, interventions will be switched. Pain level and infant distress will be measured using NIPS and infant distress scale respectively, physiological parameters, such as oxygen saturation and heat rate, will also be recorded using pulse oximeter.
Conclusions: Reducing vaccination pain helps prevent long-term negative effects on children's health. Practitioners are responsible for managing pain during procedures using simple and cost effective and quick relief methods.
Trial Registration: CTRI: CTRI/2023/11/060179.

Keywords: Acupressure, Cold application, Pain, Intramuscular injection, Vaccination, Behavioural responses

INTRODUCTION

Injections are considered the gold standard for administering various medications through parenteral routes. Intramuscular injections, a common parenteral method, are widely used worldwide.[1] With the increasing number of vaccines, children may receive up to 20 injections by the age of two.[2] Most intramuscular vaccinations are given during early infancy.[3] Immunization prevents disease by introducing live, dead, or weakened organisms into the body.[4] Vaccines help prevent and control infectious disease outbreaks, support global health security, and play a key role in fighting antimicrobial resistance.[5] The fourth millennium development goal aimed to reduce under-5 mortality by two-thirds by 2015, with immunization playing a key role in achieving this target.[6] In 2023, approximately 105 million infants worldwide received vaccines for diphtheria, tetanus, pertussis (DPT-3), protecting them from severe illnesses, lifelong disabilities, or death. According to India's national family health survey-IV, full immunization coverage is 62%, while DPT-3 vaccine coverage stands at 78.4%. In 2021, 18.2 million infants missed their first DPT vaccine dose due to limited access to immunization and healthcare services, while another 6.8 million were only partially vaccinated.[7] Although vaccination offers significant benefits, the pain it causes can lead to anxiety and distress in many children.[8] If left

unaddressed, vaccination pain can result in pre-procedural anxiety, needle phobias, and avoidance of healthcare, including skipping recommended immunizations.[9]

Reducing pain during childhood vaccinations can help lower distress.[10] Negative emotions related to medical procedures, like vaccinations, are often overlooked. Fear is especially concerning because it has a two-way connection with pain-greater perceived pain can increase fear, which in turn amplifies pain.[11-13] Recently, more attention has been given to pain as a side effect of vaccines.[14-15] Poorly managed pain during medical procedures can lead to the buildup of fearful memories, increasing discomfort during future procedures.[16-17]

Children who have experienced vaccination pain in the past often anticipate it, showing physiological, hormonal, and behavioral reactions. These can include instability in vital signs, crying, irritability, difficulty cooperating, stress, anxiety, apnea, irregular heart rhythms, increased blood and intracranial pressure, rapid breathing, altered immune response, delayed wound healing, and changes in nervous system development.[18-20]

To minimize the long-term negative effects of pain on children and reduce the mental and physical impact of painful procedures, healthcare providers must manage pain using a variety of techniques.[21] Effective pain management not only alleviates physical discomfort but also enhances the overall quality of life.[22] With the focus on the newer trend in pediatric trauma care, significant progress has been made in pain management. This includes the use of various non-pharmacological techniques to reduce pain.[23-24]

Various techniques have been explored to alleviate the pain associated with intramuscular vaccinations. However, many of the methods investigated in research may be time-consuming, costly, or impractical in real-world settings.[25] In clinical practice, the most effective technique is often the one that is inexpensive, easy to apply, and provides rapid relief.[26] Therefore, the aim of this study is to find the effects of acupressure and cold application on both behavioural responses to pain and physiological parameters in infants receiving intramuscular injections.

METHODS

Study design

The study is designed as a randomized controlled trial with a crossover approach (Figure 1).

Sample size

Sample size is calculated on the basis of the reference study.[27] The sample size for the present study is 170. With 95% confidence level, 90% power with reference to the study sample size estimated to be 77 in each group. With 10 % attrition total sample will be 85 in each group.

Study place

The study will be conducted at immunization clinics of AJ Institute of Medical Sciences in Mangalore. Karnataka, India.

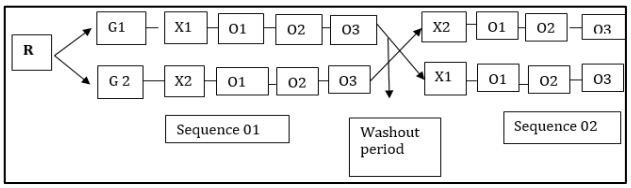

Figure 1: Schematic diagram of cross over design.
R-Randomization process, G1 – Group 1, G 2- Group 2, X1-Acupressure (LI.4): Application of acupressure X2- Cold application: application of ice cubes. O1, O2, O3: Observation of behavioral responses to pain, distress and physiological parameters during, immediately 1 minute and 5 minutes after intramuscular injection, in groups I and II. Washout period- In this study washout period is 4 weeks. Sequence 01: Group I will receive acupressure and group II will receive cold application. Sequence 02:Group I will receive cold application and group II will receive acupressure.

Eligibility criteria

The inclusion criteria for the study based on a literature review and expert opinion are as follows: Infants aged between 1 to 6 months who are receiving intramuscular injections, both male and female, whose parents are willing to provide consent for participation, medically stable infants and those receiving the first needle prick at the injection site.

The exclusion criteria are Infants receiving any injections other than intramuscular (e.g., subcutaneous, intravenous and intra dermal) infants who are not cooperative, infants who have used topical anaesthetics applied to the injection site, and infants who have used sedatives, analgesics or opioids within the preceding 24 hours.

Interventions

Acupressure (Li.4)

The application of manual pressure using thumb finger to acupoint (LI.4). LI.4 acupoint situated in the web between the forefinger and thumb on the dorsal (posterior) aspect of the hand. The Investigator will be trained by the acupuncturist and performing the intervention once for 5 minutes before intramuscular injection for 30 seconds.

Cold application

The application of ice cubes covered in double layered gauze to the vastus lateralis intramuscular injection site, 5 minutes before for 30 seconds.

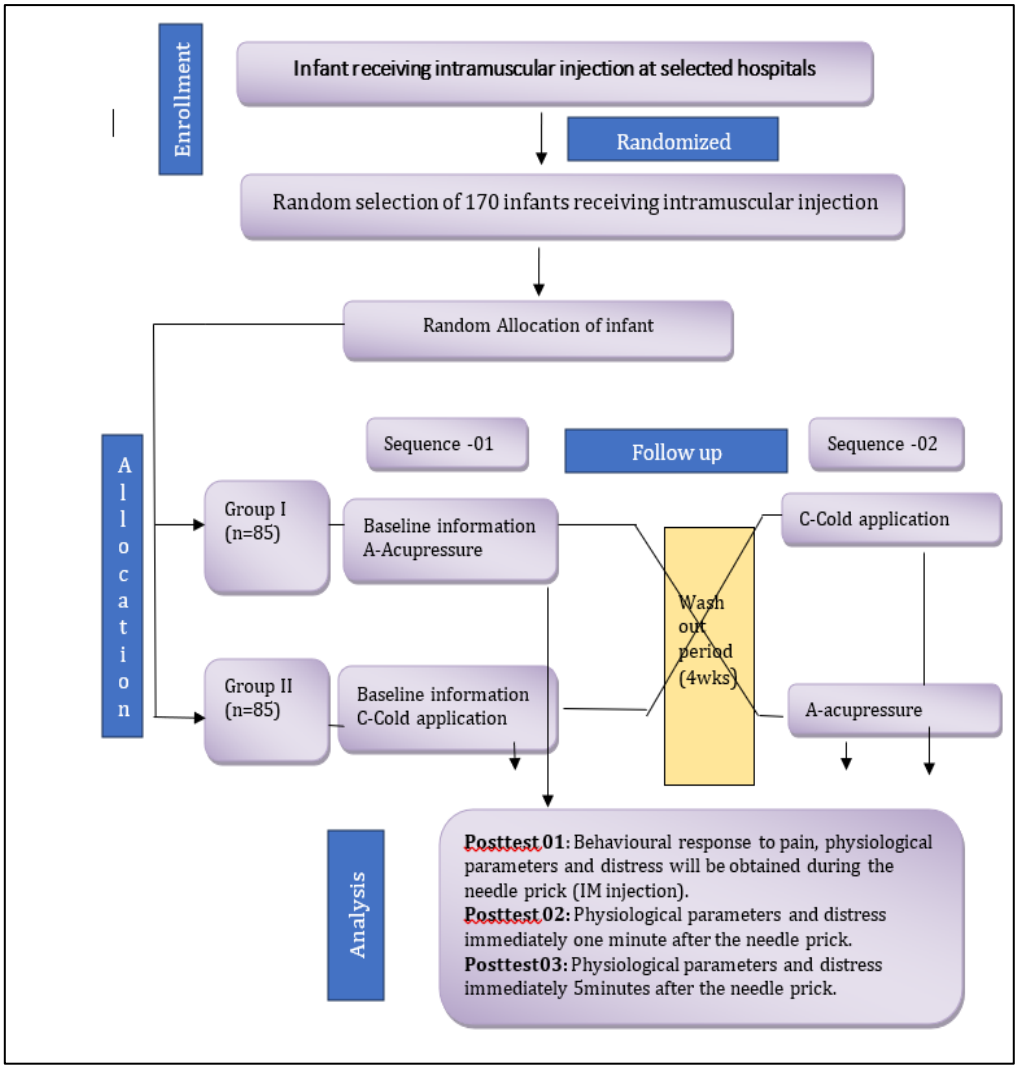

Figure 2: Study flow chart according to CONSORT.

Outcome

Post tests on both groups will be taken by the research assistant during the needle prick, immediately one minute and five minutes after the intramuscular injection. Pulse oximetry will be used to measure oxygen saturation and heart rate. To assess the behavioural responses to pain, a video recording of the child behavioural responses to pain will be done by the research assistant and the distress will be observed during the needle prick and scored in the infant distress scale. Distress, oxygen saturation and heart rate will be obtained immediately one minute and 5 minutes after intramuscular injection. Following by the assessor will score the behavioural responses to NIPS by observing the video recorded.

Randomization

A list of infants who had immunizations from 1 to 6 months will be obtained from the immunization register of selected hospitals. A random number table will be used to select the sample. The purpose of the study will be explained to parents/care givers and they will also be assured of their anonymity and confidentiality to their response. Informed written consent to participate in the study will be sought from the parents/care givers of the infants. Written consent for video recording of the child behavioural responses to pain during intramuscular injection will be obtained from parents/ care takers. Infants who meet the inclusion criteria will be enrolled.

Random allocation

An enrolled infant will be randomly allocated to the groups I and II.

Allocation concealment

A sequentially numbered opaque sealed envelope (SNOSE) method will be used. The randomization group will be written on a paper and is kept in an opaque sealed envelope. The envelope will be labelled with a serial number by the research assistant. The investigator will open the sealed envelope once the parent/care giver has consented to participate and then assigns to the treatment groups accordingly.

Blinding

The assessor will be blinded to the treatment.

Manipulation

The infant along with caregiver will be taken to immunization room. During the immunization procedure, the parents and caregiver in both groups will be allowed to calm their babies by touching and talking to them. Parents/care givers of infants will be interviewed for baseline information.

In sequence -01: Infants in group I will be applied acupressure to the LI.4 acupoint five minutes before intramuscular vaccination once for 30 seconds and Infants in group II will be applied by ice cubes covered in double layered gauze to the vastus lateralis intramuscular injection site 5 minute before intramuscular vaccination once for 30 seconds.

After 4 weeks of washout period. In sequence -02: Infants in group I will receive cold application and in group II will receive acupressure.

Control

Each infant serves as their own matched control.

Data collection

Data Collection of this trial will begin from first March 2025.

Instruments

Instruments used in this trial will include a semi-structured interview schedule, the neonatal infant pain scale, the infant distress scale, and a calibrated pulse oxymeter for measuring physiological parameters such as heart rate and oxygen saturation.

Semi structured interview schedule

It will be used to collect the baseline information. It contains 16 items like age, gender, gestational age, birth order of the baby, current weight and birth weight of an infant, educational status of parents, annual income of the family, past history of intramuscular vaccination, hospitalization, any invasive procedures, relationship of the child with the care givers who is present during the injection, when was the last feed given before vaccination, details about current health status of the child.

Neonatal and infant pain scale (NIPS)

The NIPS was developed by lawrence et al, in 1993. The interrater reliability of the tool is 0.92 and 0.97. Concurrent validity was established by correlations, ranging from 0.53 to 0.84. It included the assessment of six parameters i.e., facial expressions, cry, breathing pattern, arm and leg movement and state of arousal. The parameters were categorized according to the behavioural response of the infant.

Each behavioural indicator is scored with 0 or 1 except "cry", which has three possible descriptors therefore, being scored with a 0, 1 or 2. The maximum pain score of tools is 7 and minimum is 0. Level of pain is categorized into,0-2 = mild to no pain, 3-4 = mild to moderate pain, >4 = severe pain.28permission was obtained from the author.

Infants distress scale

This scale is adopted from Alexia E. Metz et al, permission was obtained from the author to use this scale in present study. As per the author reply infant distress was assessed by parents in their study. In current study infant distress after intramuscular injection will be assessed by the researcher. So, planning to do inter rater reliability of the tool. The distress scale is measured on a 0 to 5 point scale. Ranging from sleeping to inconsolable screaming. The score categories are 0=sleeping, 1= No distress,2= minimal distress, 3=moderate distress, 4=maximal distress, 5=severe distress.

Worksheet for physiological parameters

Physiological parameters will be assessed using calibrated pulse oximeter. The heart rate and oxygen saturation will be marked in the worksheet.

Statistical method

The gathered data shall be analysed using descriptive statistical parameters such as mean, median and standard deviation etc., and inferential statistical tests such as chi square test, unpaired ‘t’ test and Karl Pearson correlation coefficient, and the Bonferroni test will be conducted to determine the group causing the significant difference. A statistical package SPSS version 23.0 will be used to do the analysis. $P<0.05$ will be considered as significant.

Harm

In this trial, all unexpected and undesirable effects on the child will be recorded by the researcher and followed up via phone calls.

Ethical consideration

The purpose of the study will be explained to parents/care givers and they will also be assured of their anonymity and confidentiality to their response. Informed written consent to participate in the study will be sought from the parents/care givers of the infants. Written consent for video recording of the child behavioural responses to pain during intramuscular injection will be obtained from

parents/ care takers. Permission obtained from institutional ethics committee (AJEC/REV/02/2023).

DISCUSSION

Various interventions are employed either individually or in combination to reduce the physiological discomfort and pain that infants experience both before and after vaccines.[29-34] Although a variety of interventions have been examined, few studies have compared them to determine whether one might be better than another also the results from these studies are not conclusive because of small sample size, methodologic limitations, and contradictory findings, and an interventions are carried out independently at the different time period so the result of the studies are not conclusive, Hence, the investigator interested to test the effectiveness of interventions under randomized controlled condition.

CONCLUSION

Promoting a positive vaccination experience for children is essential to reducing needle fear and ensuring long term acceptance of immunization. Implementing effective interventions to minimize pain and discomfort during vaccination can create a comforting environment for the child. Conducting well designed randomized controlled trials can provide conclusive evidence and guide the implementation of effective strategies in clinical practice, ultimately improving the vaccination experience for infants and care givers.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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