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☑ Knowledge translation and advances in health and nursing practices

Glucose and reflexology for pain relief during arterial puncture in neonates: a protocol

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Glicose e reflexoterapia para alívio da dor durante punção arterial em neonatos: um protocolo

Glucosa y reflexoterapia para alivio del dolor durante la punción arterial en neonatos: un protocolo

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ABSTRACT

Objective: To present a study protocol to compare glucose and reflexology in pain relief in neonate intensive care during arterial punctures.

Methods: A randomized, controlled, double-blind clinical trial protocol will be carried out at a teaching hospital maternity, with30 newborns admitted to neonate intensive care who are to undergo blood collection by arterial puncture. They will be randomly assigned to a control group (25% glucose) or an intervention group (foot reflexology). The primary outcome will be neonate pain scores during and after arterial puncture. Secondary outcomes will be crying time and variation in neonates' vital signs during and after the arterial puncture procedure. Registration number RBR-639bff.

Discussion: The results of this trial will provide new insights into the most appropriate intervention for the relief of neonate pain during painful procedures.

Keywords: Glucose. Reflexotherapy. Pain management. Infant, newborn. Punctures.

RESUMO

Objetivo: Apresentar um protocolo de estudo para comparar a glicose e reflexoterapia no alívio da dor em terapia intensiva neonatal durante a punção arterial.

Método: Protocolo de ensaio clínico randomizado, controlado, duplo-cego, será realizado em 30recém-nascidos internados em terapia intensiva neonatal de uma maternidade escola que apresentem indicação de coleta de sangue por punção arterial. Serão distribuídos aleatoriamente em grupo controle (glicose 25%) ou grupo intervenção (reflexoterapia podal). O desfecho primário será escores de dor neonatal durante e após a punção arterial. Os desfechos secundários serão o tempo de choro e variação nos sinais vitais dos neonatos durante e após o procedimento da punção arterial. Número do registro RBR-639bff.

Discussão: Os resultados deste ensaio fornecerão novos conhecimentos sobre a intervenção mais adequada para o alívio da dor neonatal durante procedimentos dolorosos.

Palavras-chave: Glucose. Reflexoterapia. Manejo da dor. Recém-nascido. Punções.

RESUMEN

Objetivo: Presentar un protocolo de estudio para comparar glucosa y reflexología en el alivio del dolor en cuidados intensivos neonatales durante la punción arterial.

Método: Protocolo de ensayo clínico aleatorizado, controlado, doble ciego, en 30 recién nacidos en cuidados intensivos neonatales en la maternidad de un hospital escuela, que necesiten extracción de sangre por punción arterial. Serán asignados aleatoriamente a un grupo control (25% de glucosa) o a un grupo de intervención (reflexología podal). El resultado primario serán los escores de dolor neonatal durante y después de la punción arterial. Los resultados secundarios serán el tiempo de llanto y la variación en los signos vitales de los recién nacidos durante y después del procedimiento de punción arterial. Número de registro RBR-639bff.

Discusión: Los resultados de este ensayo proporcionarán nuevos conocimientos sobre la intervención más adecuada para el alivio del dolor neonatal durante los procedimientos dolorosos.

Palabras clave: Glucosa. Reflejoterapia. Manejo del dolor. Recién nacido. Punciones.

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INTRODUCTION

Hospitalized newborns need special attention due to the fact that their development may become limited[1]. Generally, this hospitalization takes place in Neonate Intensive Care Units (NICU), spaces for the provision of care to newborns in critical or risk states. These spaces provide assistance using specific technological resources and specialized human resources[2].

In this setting, hospitalization leads to the exposure to a high number of painful procedures, although most of them is necessary to efficiently guarantee survival[3]. Hospitalized neonates are exposed to approximately 70 stressful interventions every day. This can lead to several neurological deficits during NICU hospitalization[4].

Nonetheless, many painful procedures, such as venous punctures, surgeries, circumcisions, and vein dissections are carried out with no use of analgesics by the multiprofessional team, which can harm the neurobehavioral and cognitive development of the newborn both in the medium and the long term[5]. This topic has seldom been addressed for many decades, due to the perception that neurological immaturity made it so pain perception was limited or nonexistent[6]. Thus, there is a clear gap in the theoretical-practical knowledge of these health workers in regard to neonate pain management, as well as inadequate or insufficient use of analgesic therapies to reduce pain[7].

It is undeniable that the inability of the newborn to communicate verbally makes the management of pain more complex. Therefore, evaluation in this context resorts to instruments and forms of measurement such as scales, questionnaires, and schemes for systematized observation which have been created and standardized to decode the language of pain, facilitating records and the improvement of pharmacological or non-pharmacological therapeutic conducts[8].

The application of some non-pharmacological measures before painful procedures has become a form of health care planning that must be carried out in hospitalized newborns[3]. In regard to these measures, the use of oral glucose, as it stimulates endorphin secretion, is efficient for pain reduction[7]. Small quantities of glucose or sucrose, when placed on the anterior region of the tongue of the neonate two minutes before painful stimuli, can guarantee lower pain scores[9].

In Brazil, the gold standard for the use of sweetened solutions are glucose solutions, since they are available in manufactured vials in 25% and 50% concentrations. Administering these solutions directly on the tongue of the newborn, about two minutes before painful procedures, leads to the release of endogenous opioids, which have intrinsic analgesic procedures, blocking pain pathways[10]. This is corroborated by a protocol developed to manage pain, where the author states that the use of 25% glucose is the most commonly used in many procedures that cause pain from mild to severe, and can be associated with pharmacological or non-pharmacological measures[11].

Reflexology or zone therapy, in addition to all of its benefits, can also be used as a non-pharmacological method. This is a therapeutic massage using the digital pulps. It is based on the idea that human bodily structures have reflex areas situated in the auricular regions, as well as in hands and feet, and, as soon as these are provoked through massage, they can lead to responses from all organs, glands, and muscles, from specific regions or, or from the reflex points themselves[12].

This technique as presented promising results in the treatment of painful conditions. After the pressure receptors in these areas are stimulated, they should be able to send messages to the central nervous system (CNS) and, then, the regulatory references would reach the desired places. In addition to this reflex effect, effects described include tension reduction, stress, general relaxing effect, improved blood circulation, management of good health, and promotion of wellbeing[13].

Considering the above, this study is justified by the number of painful invasive interventions carried out in neonates during their stay in NICU; by the lack of non-pharmacological methods to reduce the pain of neonates exposed to arterial punctures in hospital environments; and by the need to compare the efficiency of non-pharmacological measures to reduce the pain of the newborn and guide the assistance of nursing in patients who undergo arterial punctures.

Considering this reality, this study is justified due to its uniqueness, as it compares the efficiency of glucose and reflex therapy in the relief of neonate pain. Regarding the patient, the management of pain can help avoid significant repercussions, both regarding the immediate damage the invasive pain procedure can cause, including vital sign alteration, agitation, and longer procedures, and the long term damage, that can lead to alterations in pain thresholds and in the neurological development of the newborn[3,14].

Consequently, this study aims to present a study protocol to compare glucose and reflexology as tools to relieve the pain during arterial punctures of neonates in intensive care.

METHOD

This protocol adheres to the declaration of Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)[15] and Consolidated Standards of Reporting Trials (CONSORT)[16].

Design of the study

Protocol for a randomized controlled clinical trial with a double blind design (instrument collector, nurses that will carry out the puncture, and statistician), which compares glucose and feet reflexology in the reduction of the pain of neonates in intensive care therapy (record number of this study: ensaiosclinicos.gov.br – identification RBR-639bff). Research participants have the same odds of receiving the intervention proposed or not, and the groups must present similar characteristics, to allow analysis about the effect of the intervention on the outcome of a group on the other.

This study is one of the requirements for a doctor's degree. The thesis and its results will be presented to the scientific board of the Universidade Federal do Rio Grande do Norte – UFRN.

Participants

This study will include neonates (up to 28 days of life) with ≥ 32 weeks of gestational age or who weighed ≥ 1500g at birth, who had to undergo lab exams/gasometry/blood culture using arterial punctures will be included in this study. Newborns with a diagnosis of perinatal asphyxia (Apgar index < 5 in 5 minutes), with no suction reflex, who are using sedatives or analgesic, who are using invasive ventilation support through orotracheal tube, as well as those with congenital malformation, neurological syndromes and manifestations, and children of drug users were excluded from the research.

The study will be carried out in the Maternity of the Teaching Hospital Januário Cicco (MEJC), at the Universidade Federal do Rio Grande do Norte (UFRN), in the Neonate Intensive Care Unit, specialist in high-risk pregnancies and births in the state of Rio Grande do Norte. The sample will be probabilistic, simply randomized, formed by 30 neonates hospitalized in the NICU of said maternity, who are recommended to have their blood collected for exams through arterial puncturing. The study will include patients who attend to the inclusion criteria, requiring the guardian of the children to sign the Free and Informed Consent Form (FICF).

Ethical Aspects

The research will follow the ethical precepts of the Helsinki Declaration and the ethical precepts for research with human beings from Resolution 466/2012, from the National Council of Health, in order to respect human health and protect, especially, the participants of scientific studies that involve human beings.

This trial was submitted to the direction of the MEJC for authorization and to the Research Ethics Committee at UFRN, being approved under CAAE 23720419.5.0000.5537. It was recorded in the *Registro Brasileiro de Ensaios Clínicos* (REBEC – the Brazilian Register of Clinical Trials) under No. RBR-639bff. Patient participation will be voluntary after the FICF is signed by the responsible parties, who can abandon the research whenever they wish to do so with no harm to the treatment, judgment, or penalties.

The researchers will guarantee the anonymity of the participants, ensuring that data about them will remain confidential, protecting their identity, including any type of information that could identify them. Two copies of the FICF will be provided, both signed by the legal guardian of the participants and the main researcher.

The main investigator is the one responsible for storing data and files, terms and samples for at least five years after the research is concluded.

Any changes in protocol that become necessary will be informed and the relevant elements will be altered (trial records, Research Ethics Committee, funding agency, and journal). Any doubts about the study will be adequately clarified by the researchers during the initial evaluation period and for the duration of the study.

Interventions

The neonates in the control group (CG) will receive 1ml of glucose 25% orally (for term newborns) or 0.5ml of glucose 25% (for pre-term newborns), two minutes before arterial punctures in both cases. In the intervention group (IG), feet reflexology will be applied in the analgesia points B-62, R-3, and R-1 two minutes before the procedure. The application of 25% glucose and of reflexology on the feet will be carried out by the same neonate nurse, trained to perform these procedures. After the intervention is applied, the neonate will remain two minutes without being handled. Then, the arterial puncturing procedure will be carried out, in order to avoid a biased result. Two minutes is time enough for endogenous opioids, which have analgesic effect, to be releases[17,18].

Study protocol

The study will be coordinated by a researcher with more than 10 years of experience in research. An assistant researcher will be responsible for recruiting and applying the intervention in the control and intervention groups. A second researcher will fill in the data collection instrument, without knowing to which group each participant belongs.

All stages of data collection and analysis will be supervised by the main investigator.

The application of the data collection instrument will be carried out during arterial puncture by a nursing graduation student previously trained; this instrument will include the NIPS-Brazil as its pain assessment instrument. The student will also be blinded, since, after filling the instruments at bedside at a first moment, the student will leave the room during the intervention and go back when the intervention is finished, to continue with the other stages. The puncturing procedure will be carried out by the nurses who are working in the direct care of the hospitalized neonate. These ECR interventions are described in Figure 1.

A pilot test will be carried out using data from the first two participants of each group (a total of four participants), after which it will be used to perfect and adapt the instrument and its methodological approach in such a way as to answer the objectives and improve the adherence to the intervention protocol. According with Canhota (2008)[19], the number of participants for the pilot test does not need to be greater than 10% of the sample desired. As a result, two neonates per group is more than enough for its application. The participants of the pilot study will not be included in the final sample.

The data collection instrument used is formed by three topics: A) Mother's data: age, educational level, marital status, reason for hospitalization, whether there were prenatal consultations, and number of prenatal consultations; B) Data regarding delivery and the newborn – date of birth, gestational age, type of delivery, weight at birth, sex, Apgar in the 1st and 5th minutes, and reason for hospitalization; C) Evaluation of pain during arterial puncturing through the NIPS-Brasil scale and other parameters – time of the procedure, number of punctures, crying time, complications during and after the procedures, medications being used, devices being used, oxygen saturation, cardiac frequency, NIPS scale. It should be noted that oxygen saturation, cardiac frequency, and the NIPS scale will be evaluated in three moments: rest – before intervention; during arterial puncturing; and after arterial puncturing.

The NIPS scale is formed by five behavioral variables: facial expression, crying, arms, legs, and state of consciousness; and one physiological variable: breathing. Each variable has two items which should be scored as 0 or 1 *(except in crying, which has three items that should be scored from 0 to 2). Each item has an operational definition and the score of the scale varies from 0 to 7 points, with a score above 3 indicating that there is pain[20].

Moments of evaluation

Newborns will be evaluated at three different moments during the experiment:

1 - Before intervention (glucose or feet reflexology);

2 - During arterial puncturing;

3 - After arterial puncturing.

In these three moments, the neonates will be evaluated by using the NIPS scale (Neonate Infant Pain Scales), as well as an Alfamed multiparameter monitor (to evaluate the newborn's oxygen saturation and cardiac frequency).

Outcomes of the study

The primary outcome of the study will be the neonate pain scores during and after arterial puncture, according with the NIPS. The NIPS evaluates facial expression, crying, legs, arms, state of consciousness, and breathing. Its score varies from 0 to 7, indicating that the neonate is feeling pain when the score is above 3[20].

The secondary outcomes will be crying time and variations in the vital signs of the newborns during and after the arterial puncture. The crying time is indicated by how long the newborn cries (weak or strong crying), counting from the moment the arterial puncture starts to the, which will be verified by the researcher that will fill in the data collection instrument. The variation of the vital signs will be determined by the evaluation of the oxygen saturation and of the cardiac frequency of the neonate using an Alfamed monitor, which will be checked before intervention, during arterial puncture, and after arterial puncture, by the researcher who will fill in the data collection instrument.

Sample size

The sample size was calculated using the software G Power, version 3.1.9.2[21]. A study by Lima *et al.* (2017)[22], which evaluated the NIPS score, found that the group with 25% glucose and non-nutritive suckling showed the following results in regard to mean and standard deviation 3.3 ± 2.1 and 5.6 ± 1.6, with a Cohen effect size of 1.23[23]. We can observe, considering the power of the test of 0.82, a level of significance of 5%, and, as a result, estimating 20% of losses, the estimated sample size was 30 participants, 15 in the control group (glucose 25%) and 15 in the intervention group (feet reflexology). The participants (two from each group) from the pilot study will not be included in the sample of the study after it is concluded.

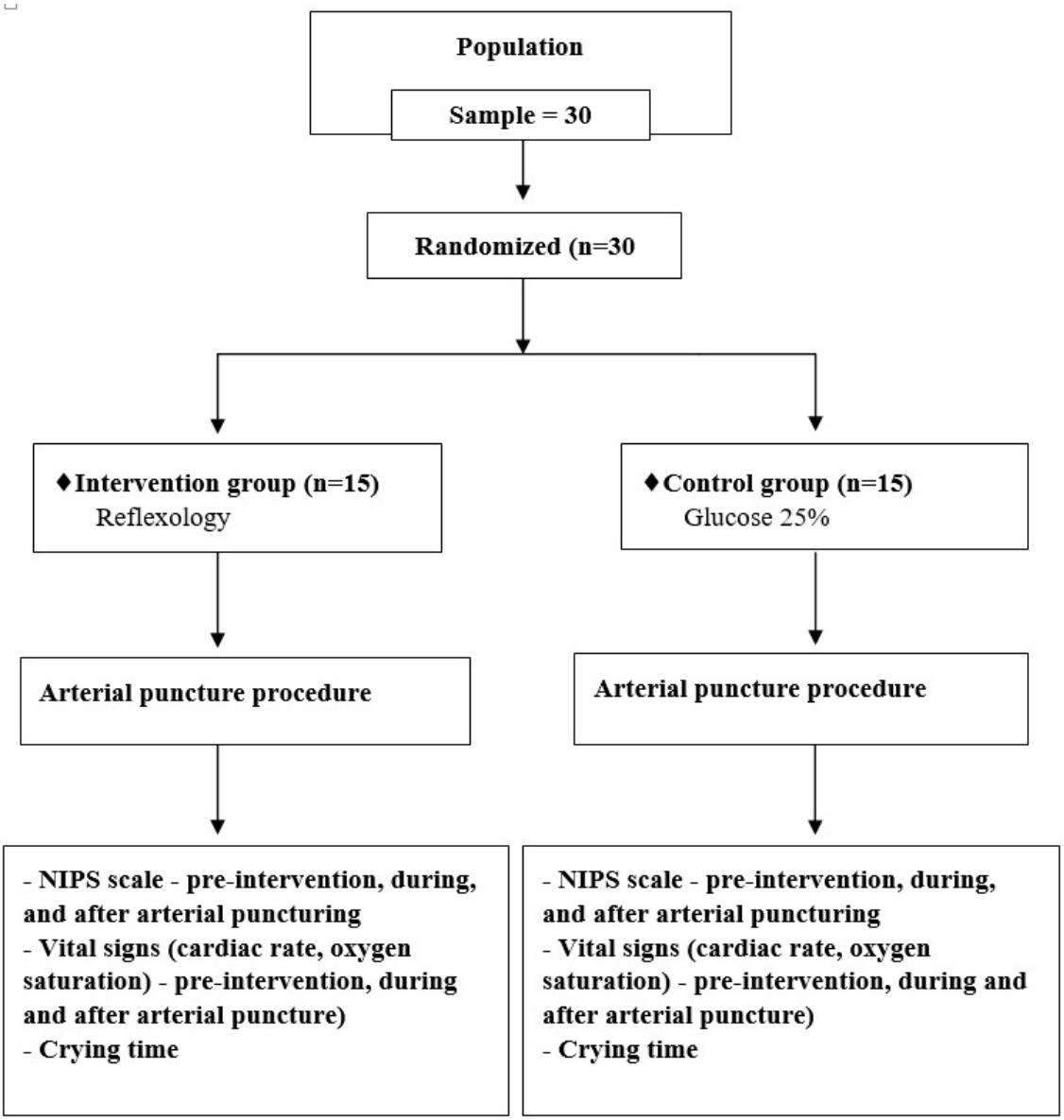

Figure 1 – Flowchart of study interventions. Natal, Rio Grande do Norte, Brazil, 2022
Source: Research data, 2022.

The losses and abandonments will be carefully registered, to guarantee the reliability of the research. If the guardian of the participant in the sample decides to abandon the study, this participant will be removed from collection, and another one will be inserted in their place.

Randomization

The sample will be formed by 30newborns that will be randomly divided in two groups: 15 patients for the control group (CG) – use of 25% glucose; 15 patients for the intervention group – feet reflexology. The groups will be divided on the website *www.randomization.com*, using the block design (1:1; CG or IG). It stands out that all patients will have the same odds of being allocated in any group. This randomization method aims to minimize confusion biases.

Blinding

The professionals who will perform the puncturing of the artery, the person responsible for filling in the data collection instrument, and the statistician that will analyze the data collected will not have access to the details of the characteristics of the group. This makes biases in favor or against the treatment being tested highly unlikely.

Statistical analysis

Information collected will be stored and analyzed using a computerized database created using Microsoft Office Excel and Statistical Package for the Social Sciences (SPSS), version 20.0. The study will use descriptive and inferential analyses and the data will be exposed using tables and figures.

The descriptive treatment will use relative and absolute frequencies and mean and standard deviation or medians and interquartile intervals, depending on the normality of the variables. To analyze the normality of data distribution, the Kolmogorov-Smirnov test will be used; to compare the study groups (control group – glucose; intervention group – feet reflexology), Student's T-test or Mann-Whitney's will be used, depending on data distribution. Pearson's chi-squared will be used to evaluate the independence between nominal variables. The significance level adopted will be 5% for all analyses.

DISCUSSION

This protocol involves a randomized trial that will compare glucose and feet reflexology in the relief of neonate pain due to arterial puncturing. The strengths of this research include: 1) a double-bind research method that avoids ethical issues and controlled randomization; and 2) the ability to evaluate both behavioral and physiological outcomes in the reduction of neonate pain. The only limitation of this study is the scarcity of studies on feet reflexology in newborns.

The primary outcome of the study will be neonate pain scores in the arterial puncturing, evaluated using the NIPS score. The secondary outcomes will be crying time and variation in the neonates' vital signs during the arterial puncturing. These two other outcomes put together represent the most relevant benefits after interventions for the relief of neonate pain.

On one hand, the use of oral glucose is currently very common in NICU care, being considered as a gold standard. On the other hand, reflexology is a new, low-cost strategy. However, there are still no evidence showing which intervention is more effective in neonate environment.

The results of this trial will provide new knowledge in regard to the best intervention to relief neonate pain during painful procedures.

Study Status

This study is currently in its data collection stage and is expected to be concluded in July 2023.

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