

The Z-Track Technique as a Pain Management Strategy for Neonates During Intramuscular Injections: Insights from a Randomized Controlled Trial

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ABSTRACT

Background: Intramuscular injections such as vitamin K supplements are very common within the first days of neonatal life and are deemed painful; therefore, nurses play a vital role during intramuscular injections by employing various non-pharmacological strategies to mitigate pain while taking into consideration ethical principles. **Objectives:** To assess the effects of using the Z-track technique (ZTT) as a pain management strategy for neonates during intramuscular injections. **Methods:** A Randomised Controlled Trial (RCT) that adopted a single-blind prospective design was performed on 80 term neonates who underwent vitamin K intramuscular injection during their first few hours of life. The sample were randomised into two groups: 40 neonates in the ZTT (interventional group) and 40 neonates in the control group. The experimental group received ZTT during intramuscular injection, and the control group received the standard method of injection. The main outcome assessment was the Neonatal/Infant Pain Scale (NIPS). **Results:** The NIPS mean scores were compared statistically, and a significant statistical difference was detected between the study and control groups (p value = 0.000), resulting in a lower pain score in the experimental group (3.28 ± 1.08) than the control group (4.53 ± 1.26) with a mean difference of -1.25. **Conclusions:** The study concluded the utilising of the ZTT is considered an effective non-pharmacological method in alleviating pain associated with the neonatal intramuscular injection of vitamin K.

Keywords: Intra- Muscular Injection; Neonate; Pain Management; Z- Track Technique

INTRODUCTION

Neonates go through a number of painful and invasive nursing procedures that are part of the required neonatal care within their first days of their neonatal life. These procedures may include administering vitamin K supplements (Hand *et al.*, 2022) intramuscularly that help to prevent neonatal haemorrhage, blood sample collection through heel lancet or from a vein, and also intravenous injection or injection of the vastus lateralis muscle (Mohamed *et al.*, 2019). For this group of newborns, adequate postnatal vitamin K intake appears to be essential. In order to prevent haemolytic disease in newborns, vitamin K is frequently administered as a prophylactic after birth (Patel *et al.*, 2022). The phenomenon of pain experienced by neonates as a result of medical procedures has garnered significant concern over the past two decades. On average, a neonate undergoes approximately 7 to 17 medical interventions daily during the initial 14 days postnatally (Sankar *et al.*, 2016).

Research demonstrates that exposure to pain during early childhood is correlated with the manifestation of violent behaviour and self-destructive tendencies during adolescence (Beena *et al.*, 2025). Other consequences of uncontrolled or unmanaged pain stimuli include permanent interruption to cognitive growth and possibly neonates' development rate due to interfering with the brain growth flexibility and thereby interference in subsequent pain responses (Taghinejad & Suhrabi, 2025). Managing pain for control thereby should be part of the neonate routine care performed during nursing and medical procedures (Lago *et al.*, 2025).

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In recent years, the importance of non-pharmacological approaches has increased due to the potential side effects of pharmacological methods (Al-Shammiry & Al-Fayyadh, 2024), such as respiratory depression, apnoea, and bradycardia. As a result, nursing research has concentrated on these methods. While pain experienced by newborns after normal vaccination is not considered a symptom of disease, it has been suggested that non-pharmacological pain relief techniques are preferable. Non-pharmacological treatment options include things like using skin tap techniques to distract from pain (Sahoo *et al.*, 2025), listening to music (Brown *et al.*, 2022), and therapeutic applications of heat and cold (Güngör & Öztürk Şahin, 2020). The ZTT method is deemed as one of the prevalent non-pharmacological strategies and techniques that are utilised while administering injections (Said & Shehata, 2016). The way this technique works is by retracting the skin by using the non-dominant hand on the injection site of the muscle approximately 2.5 cm to 3.5 cm to the lateral side, then inserting the tip of the needle into the muscle at a ninety-degree angle, and the skin is immediately released to return to its normal status once the needle is pulled from the muscle following the drug injection (Baş & Keçeci, 2023). Considering the ZTT usage in practice is not very common, but there is evidence supporting the technique's effectiveness and recommending its routine use (Sah & Maskey, 2020).

Assessment and management of pain should be taken into account, as inappropriate assessment may complicate the process of pain management (Bachi & AL-Fayyadh, 2022). In one article, 'The Fifth Vital Sign: Implementation of Neonatal Infant Pain Scale' describes a Californian hospital's implementation of NIPS and the education provided to nurses and its utilisation in clinical practice (Attar *et al.*, 2022; Ismail & Ali, 2025). NIPS was found to be an accurate tool in assessing pain and easy in application by nurses (Bhattacharya & Batra, 2020). Reviewing the previous literature provided evidence on the effect of the ZTT on adult patients, such as in a study conducted by Yilmaz *et al.* (2016), which concluded that using the ZTT is effective in reducing pain during intramuscular injection for adult patients. Another study by Tambunan and Wulandari (2015) utilised the ZTT air locking technique and found it effective in reducing pain in intramuscular injections. However, no study was conducted on the paediatric population to determine the efficacy of the technique, and this explains the purpose of conducting this study to address the knowledge gap and generate evidence-based practice to be used by paediatric nurses performing intramuscular injections of neonates.

Alternative Hypothesis: (H1)

Term neonates administered intramuscular injections using the ZTT will experience a marked decrease in pain scores as opposed to those not receiving the technique.

METHODOLOGY

Study Design and Trial Registration

The study was a prospective randomised controlled clinical trial with a parallel group design. The trial was registered at <https://clinicaltrials.gov/study/NCT06793618> with reg. no. NCT06793618. The study took place between November 25th, 2024 to January 24th, 2025. The study adhered to the guidelines outlined in the Consolidated Standard of Reporting Trials (CONSORT 2010 checklist).

Study Setting

This research took place in Al Muthanna governorate / Al Muthanna health directorate, at the Feminine and Children Educational Hospital in the post-natal ward. Neonates delivered by caesarean section are transferred to the postnatal ward, which is a part of the neonatal intensive care unit, for assessment and stabilisation before being scheduled to be returned to their mothers/legal guardians, during which the neonate receives various procedures, including intramuscular injections of hepatitis B vaccine and vitamin K injection, making it the place where neonates receive their first intramuscular injection.

Study Sample

The study was carried out on healthy term neonates admitted to the postnatal ward immediately after delivery by caesarean section. A simple random sample technique was utilised to select neonates to be part of the study. This random technique provides the advantage of removing any bias in the sample selection (Lim & In, 2019). After the newborn babes were put in the incubator, the paediatrician examined the newborns and provided written orders for nurses regarding injecting the neonates with vitamin K supplementation

provided written orders for nurses regarding injecting the neonates with vitamin K supplementation intramuscularly. Those neonates were the target of this study. The website random.org was used to generate the randomisation sequences for allocation into study or control groups. The sample size was determined using G power analysis (G*Power v3.1.9 software) and was eighty) term neonates allocated into the study and control groups. Figure 1 shows the sample enrolment flowchart.

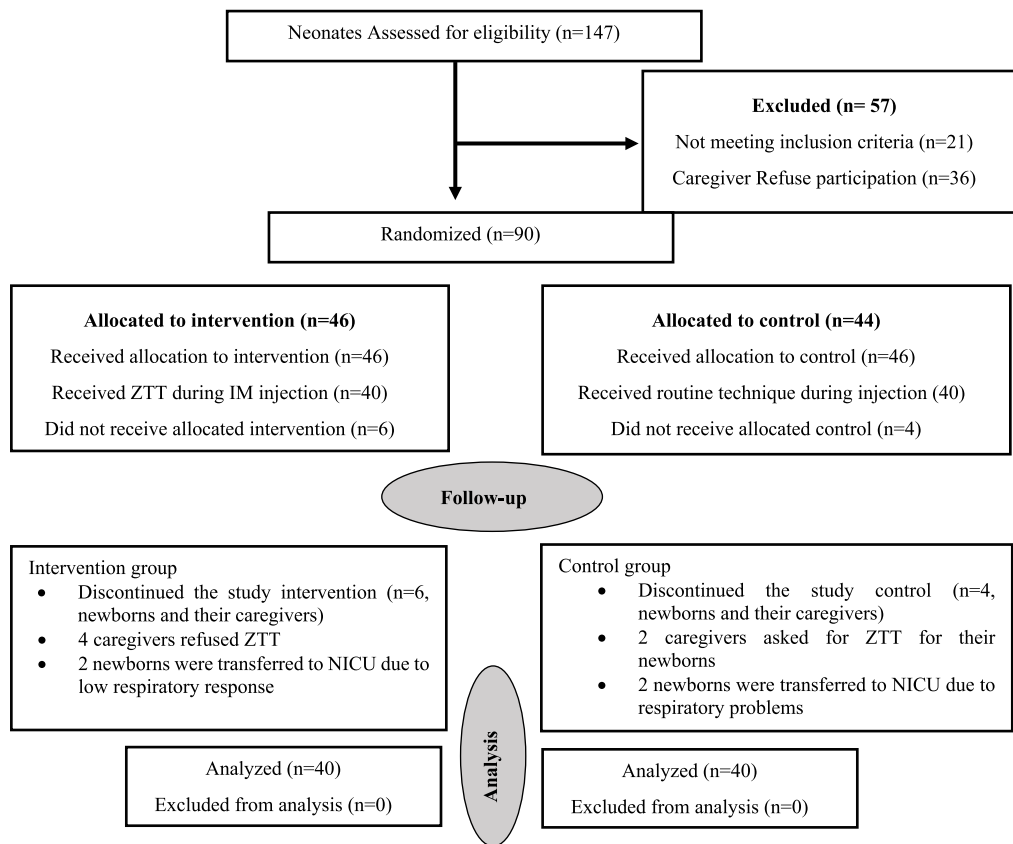


Figure 1: Study Sample Flow Chart

Sample Size Determination

Power analysis was performed using the G*Power (v3.1.9) software adopted by Grove and Grey (2019) to determine the sample size. The effect size was found to be Cohen's $w = 0.4$, calculated based on previous research conducted by Kaya and Zengin (2023) with a probability error of $\alpha = 0.05$ and $\beta = 0.10$. A sample size of 70 neonates would be sufficient to detect significances in the sample. Considering withdrawals from the study and possible bleeding after injection, the total sample size was 80 healthy term neonates.

The Criteria for Selection of the Study Sample

Inclusion Criteria

The researchers targeted healthy neonates delivered between the 37th and 42nd weeks of gestation through caesarean section, who weighed between 2500 and 3500 grams and achieved an Apgar score of 8 or more. Those who did not receive any analgesics or any invasive procedures prior to the intramuscular injection of vitamin K. This was due to the possibility of interfering with pain perception in neonates and thus affecting pain measurement (Lindbeck *et al.*, 2023).

Exclusion Criteria

Neonates suffering from any congenital anomalies, having low birth weight, considered preterm,

delivered normally (normal vaginal delivery), and also those who received hepatitis B vaccination prior to transfer to the postnatal ward were not included in the study.

Data Collection Tools

Newborn Clinical Data Form

The form consisted of three items reported by the observer (nurse), including the newborn's gestational age in weeks, gender, and birth weight in grams.

Neonatal/infant Pain Scale (NIPS)

A scale developed specifically for newborn infants. The scale consists of 6 criteria (face expression, cry, patterns of breathing, leg and arm movements, and arousal status) and is recommended for use for pain assessment in children less than 1 year old.

The following explains the scoring system using this scale:

The criterion (crying) has 3 scorings (0-1-2); however, all the other criteria have 2 scorings (0-1). A score of zero represents no pain, 1-2 is considered mild pain, 3-4 is moderate pain, and 5-7 is severe pain.

Study Instrument Validity/Reliability

The early questionnaire was presented to a panel of 12 experts who had more than 10 years of experience in nursing science to assess for clarity and whether the questionnaire is good enough to achieve the desired goals of the study. Changes were limited to demographic items only.

Lawrence *et al.* (1993) developed NIPS, and the validity and reliability tests were conducted by Kanbur *et al.* (2021) in their Turkish study. The values of the Cronbach test in the original study ranged from 0.87 to 0.95. It was reported that the Turkish study to obtain the validity and reliability for the NIPS scale resulted in a range from 0.83 to 0.86 using the Cronbach Alpha coefficient test.

Procedures

In the postnatal ward where the study was conducted, routine care (cleaning, drying, nasal care) is carried out under a radiant heater. Vitamin K is administered during the first few hours of life. The injection procedure protocol is provided in table 1. The newborn stays in the postnatal ward until they are actively feeding and show no sign of distress; then they are delivered to their mother/legal guardians (father, grandmother). In this study, the newborn pain was evaluated by NIPS, and pain was evaluated at one timepoint during the Intramuscular Injection procedure. In the study, neonates who received ZTT during the IM injection were included in the experimental group, while those who received the IM injection with the routine method were included in the control group. All interventions to the newborns in the control group were performed under a radiant heater. All newborns should receive vitamin K prophylaxis, as it has been proven that oral and intramuscular prophylactic vitamin K given after birth are effective for preventing classical Haemorrhagic Disease of the Newborn (HDN) (Jullien *et al.*, 2021). Vitamin K deficiency in an infant can cause bleeding known as HDN or Vitamin K Deficiency Bleeding (VKDB) (Clarke *et al.*, 2015). When the IM route is chosen with standard precautions in the anterolateral thigh, the risk of local hematoma, infection, and neuromuscular damage at the injection site is very low (Jullien *et al.*, 2021).

Table 1: Vitamin K Intramuscular Injection Protocol

Performing hand hygiene and wearing nitrile gloves
Using 1 ml syringe to draw Vitamin K supplement 0.5ml
Using the left vastus lateralis muscle site for injection
Wiping Area cleansed with alcohol and allowed it to air -dry before needle insertion
Insertion angle is 90°
After needle insertion Aspiration is performed
Needle withdrawal at the same angle as insertion
Site not massaged after the injection
Data recorded: Another investigator assessed and recorded

Intervention Group

During the administration of the injection, the neonate was in a supine position, the position of his/her legs was normally flexed, and the ZTT was adopted when administering the injection. During injection, the skin was pulled laterally, and, thereby, the cutaneous and subcutaneous tissues were moved by approximately 1 to 2 cm. The researcher who injected the drug used the nondominant hand to displace the cutaneous and subcutaneous tissues, and a co-observer recorded the pain score after needle withdrawal on the neonatal clinical data form.

Control Group

During the administration of the injection, the neonate was in a supine position, the position of his/her legs was normally flexed, and the injection was administered using the routine method. During the routine injection technique practice, the skin was not pulled laterally. A co-observer (nurse) recorded the pain score on the neonatal clinical data form.

Data Collection

Before starting the study, the purpose of the study, the content of the forms, the interventions and how the data obtained in the study will be used were explained to the primary carer of the newborns, and then their verbal and informed consent was obtained. Explaining to the primary carer that participation and withdrawals are their choice and without any consequences and that participation is without any sentiments or rewards.

Only newborns from parents who gave their informed consent were included in the study. The nurse who performed the injection procedure was a bachelor's degree paediatric nurse who had 15 years of experience handling neonates in the neonatal wards, which makes them most suitable to perform the procedure, ensuring the successfulness of the procedure and the intervention, and also guaranteeing the safety and avoiding any unnecessary injury to the neonate.

The other academic nurse, who is the observer, had previously participated in clinical trials assessing pain levels using various outcome measurements and had previous training with using the neonatal/infant pain scale to ensure the appropriate assessment of the outcome, providing the best health outcome by accurately performing the assessment process, achieving the best health results and avoiding any bias.

Blinding/Masking

In randomised clinical trials, using a blinding method is considered part of the gold standard of the RCT methodological strength (Saltaji *et al.*, 2018). This was done by putting a foldable medical privacy screen between the neonate in the incubator and the observer nurse while performing the injection, and immediately after needle withdrawal, the observer removes the privacy screen and starts recording the pain score without knowing what the intervention applied by the first nurse was (ZTT or standard technique).

Data Analysis

The Statistical Package for Social Sciences (SPSS) version 27 was used for statistical analysis. Categorical data were represented as numbers and percentages, and numerical data as mean and standard deviation. Normal distribution was tested using the Shapiro-Wilk test and graphical analyses. Mann Whitney U test was used for comparisons between two groups of non-normally distributed quantitative variables. Pearson's chi-square test was used to evaluate categorical data. Statistical significance was accepted to be $p < 0.05$.

Ethical Consideration

The study received ethical confirmation from the Committee of Scientific Research (CSR) at the College of Nursing, University of Baghdad, Iraq, with reference number REF-37 on 6th November 2024.

RESULTS

Table 2 shows that more than half (55.5%) of neonates in the study group and half (50%) in the control group had 38 weeks of gestational age. It was also found that more than half (60%) of the study group were

males, and slightly more than half (52.5%) of the control group were females. The table shows that the mean birth weight in the study group was 2947.5 ± 288.7 and in the control, group was 2875.7 ± 255.7 . However, there were no statistically significant differences between the study and control groups regarding gestational age, sex, and birth weight, indicating similarity between groups.

Table 2: Distribution of Demographic Variables for Neonates (n= 80)

Variables	Categories	Groups				Statistical Test	
		Experimental		Control			
		Freq.	%	Freq.	%	Test	P value
Gestational week	37 weeks	1	2.5%	7	17.5%	$\chi^2= 5.74$	0.124
	38 weeks	22	55.0%	20	50.0%		
	39 weeks	14	35.0%	12	30.0%		
	40 weeks	3	7.5%	1	2.5%		
Gender	Male	24	60.0%	19	47.5%	$\chi^2= 1.25$	0.185
	Female	16	40.0%	21	52.5%		
Weight	Mean $\pm$ SD	2947.5 (288.7)		2875.7 (255.7)		T= 1.17	0.243

Freq.=frequency; %= percentage; χ^2 = chi-square; T= student t test; p value <0.05 = significant

Table 3 indicates there were 11 neonates (27.5%) who had no pain in the intervention group. Twenty-one neonates (52.5%) had moderate pain when the ZTT was applied, and the remaining eight (20%) suffered severe pain. Contrary to the findings in the interventional group, 23 (57.5%) had severe pain, 15 (37.5%) had moderate pain, and only 2 (5.0%) had mild pain in the control group.

Table 3: Association of Injection Technique with the Pain Level of the Neonates (n= 80)

Pain Level	Experimental Group		Control Group		Total	
	Freq.	%	Freq.	%	Freq.	%
Mild Pain (NIPS score 0 – 2)	11	27.5%	2	5.0%	13	16.3%
Moderate Pain (NIPS Score 3 – 4)	21	52.5%	15	37.5%	36	45.0%
Severe Pain (NIPS Score $\geq$ 5)	8	20.0%	23	57.5%	31	38.8%

Freq.=frequency; %= percentage; NIPS= Neonatal/ infant pain scale

Table 4 clarifies that the mean pain score in the ZTT group is 3.28 ± 1.08 , and the pain score is 4.53 ± 1.26 among the control group. The table shows a statistically significant difference between the groups (Mean Difference = -1.25, $P = 0.000$), indicating a very large difference between the ZTT and the conventional IM injection method. Similarly, the median of the Neonatal Infant Pain Scale score of the neonates in the experimental group (3) was lower than that of the control group (5), and this was found to be statistically and clinically significant ($P < 0.001$).

Table 4: Total Mean Score of Pain for Newborn in Study and Control Groups with Mean Differences for Neonates (n= 80)

Outcome Measurement	Experimental Group		Control Group		Mean Difference	P	Cohen's d	Interpretation	Inter-Group Comparison
NIPS	Mean $\pm$ SD	Min- max (median)	Mean $\pm$ SD	Min-max (median)	-1.25	0.000**	-1.07	Large effect size	Z: -4.36a (0.000**)
	3.28 $\pm$ 1.08	1-6 (3)	4.53 $\pm$ 1.26	1-6 (5)					

SD=standard deviation; Min=minimum; Max= maximum; $p < 0.01$ **=highly significant; a= calculated using Mann-Whitney U

DISCUSSION

Pain management is a primary responsibility of nurses working in neonatal wards. Various non-pharmacological interventions have demonstrated efficacy in preventing and relieving pain in infants undergoing painful procedures (Lago *et al.*, 2025). It is important that these methods are effective, low-risk and cost-effective. Pain response in infants is affected by factors such as gestational week, sex, and weight (Nugrawati *et al.*, 2024). In this study no statistically significant difference was found between the study groups in terms of those factors, and hence the groups were similar ($p > 0.05$). From the researcher perspective, factors such as gestational age, sex, and weight affect infants' response to pain so that the researchers focused on the homogenous distribution of these characteristics, which are thought to affect IM

pain levels, thus contributing to eliminating these confusions. These findings go with the findings of the study conducted by Elshahat *et al.* (2023), who found in their study the effect of cold and heat on pain of pentavalent vaccination and reported that no significant differences were noted between the study and control groups with regards to sex, birth weight, nutrition status and gestational age.

In the study findings reported on table 3, the pain level for the experimental group was tested to be significantly lower than the control group. This study finding is of similarity to a study conducted by Shamsalnia *et al.* (2024) on the facilitated tucking effect on reducing pain using the same outcome measurement as this research, and the study found that neonates in the study group have a lower Neonatal/Infant Pain Scale mean score than those in the control group. Another study conducted by Saji *et al.* (2024) on adult patients provided evidence on the difference between the pain levels of using ZTT and the standard method, which clarified that the majority of the study group had moderate levels of pain in the experimental group, while the control group sample had moderate to severe pain levels.

Regarding the mean score of pain as shown in table 4, applying the ZTT during IM injection resulted in a significantly lower mean pain score compared to neonates who underwent vitamin K injection using the routine method. This goes with a study by Elsaid and Abdelkhalek (2019) that concluded the usage of the ZTT method resulted in low pain scores when used during IM injections compared to using the standard method during intramuscular injections. A study by Kara and Güneş (2016) had similar results, which found that less pain is noted with the ZTT use during IM injection. Moreover, another study that was conducted in Turkey by Yilmaz *et al.* (2016) found that pain intensity was reduced when the IM sodium diclofenac was injected by using the ZTT. These results are also supported by Tambunan and Wulandari (2015), who illustrated that both the Z-track and air-lock methods resulted in less painful IM injections compared to the standard technique.

Various non-pharmacological methods have been proven to be effective in reducing intramuscular-associated pain in the paediatric population, and these include shot blockers (Yilmaz *et al.*, 2024), kangaroo mother care (Fallah *et al.*, 2017), music (Rossi *et al.*, 2018), oral sucrose (Imani & Moradi, 2019), and breastfeeding (Kaur *et al.*, 2024). Those options are cost-effective and are easy to use, and their actions and effectiveness in reducing pain have been proven during intramuscular injections. Better health-related outcomes regarding patients' experiences can be provided by employing non-pharmacological approaches (Gilbertson *et al.*, 2023).

Health care providers, and especially nurses, realised their important role in pain management for patients (Fahd & Shawq, 2023). This is related to nurses' ability to guide patients regarding alleviating pain through non-pharmacological techniques and also supporting them emotionally and cognitively. Hence, nurses have a major role in pain management for patients according to the planned treatment plan, thus contributing to patient safety (Albugami *et al.*, 2023).

Limitations

Considering the study took place in one postnatal ward, the results are limited to those neonates only. Another limitation is that the study did not include hepatitis B vaccine injection. also, the study included only term infants limited to vitamin K injections.

CONCLUSION

In the study, the researchers have reached the conclusion that the ZTT application during IM injections for neonates had an alleviating effect on the NIPS scores. Low mean pain scores in the ZTT indicating the effectiveness of using this technique. Therefore, this strategy for pain reduction can be utilized by nurses during standard injection practice and is considered cost-effective during intramuscular injections of neonates.

The study can include neonates going through vaccination, such as the hepatitis B vaccine birth dose. The effectiveness of the ZTT can be compared with the air-lock technique for neonatal injection. Future similar studies can be conducted on older children during pentavalent vaccination and on medications administered muscularly for ill patients.

Conflict of Interest

No conflicts of interest are declared by the researchers.

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