TR Istanbul University-Cerrahpaşa ID: İstanbulUCEdu

Study Protocol: June 1, 2023

the effect of two different bathing methods on vital parameters oath stress levels in preterm babies .

Clinical Trial Number: NCT06166485

WORKING PROTOCOL	
Title / Date	The effect of bathing applied in two different orders on stress level and physiological parameters in term babies / 01.06.2023
Approval of the education officer of the unit(s) where the study will be carried out.	Newborn Clinic
Name and surname of the responsible investigator, e-mail address, mobile phone, signature	Prof. dr . SEVİL İNAL inalsevil@gmail.com 05334332824
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Financial agreements between the sponsor, principal investigator or research site	
main purpose, Secondary purpose, if any hypothesis (es)	Main Purpose: This study was planned to determine the effect of bathing applied in two different orders (first the body and then the head, and the classical method of washing the whole body, starting from the head) on the stress level and physiological parameters of term babies. Hypotheses: -H0 Stress levels and physiological parameters of babies are similar in bathing methods performed from head to toe or head to toe. -H1. Babies' stress levels are higher when bathing in a sequence from head to toe compared to bathing where the head is left until the end. -H2. When bathing is performed in a sequence from head to toe, the baby's physiological parameters are more negatively affected than when the bath is left from head to end. -H3. In the bathing method in which the head is washed first, the time for babies to calm down is longer than in the method in which the head is washed last. -H4. The procedure time in the bath where the head is left last is shorter than in the bath method where the head is washed first.
Medical condition/area of treatment investigated	In this study; The effect of bathtub baths applied in two different orders on the stress level and physiological parameters of term babies will be investigated. No treatment will be applied. The research to be conducted is one of the baby care practices that are among the independent functions of the researchers who will conduct the research. The effect of baby bath applied with two different methods on healthy babies' stress level, physiological parameters, babies' calming time and procedure time will be investigated.

of the population to be examined (acceptance and exclusion criteria, age range by gender, termination criteria of the study when necessary) identification of subgroups, if any)	Criteria for inclusion in the research ; - The baby's body weight is between 2.5 - 4 kg - The baby's Apgar score is >7 - The baby does not have any health problems - Their parents agree to participate in the study -Determined as a healthy term baby Exclusion criteria from the study ; - Meconium aspiration etc. washed immediately after birth for various reasons, - Having various health problems, -Their parents did not agree to participate in the study, -It was decided to exclude low birth weight and premature babies from the scope of the research. Independent variables; Traditional bathtub bathing from head to toe and bathtub bathing methods where the head is left last Dependent variables; Stress level of babies, physiological parameters (body temperature, pulse, respiration, O_2 saturation), procedure time (bathing time), time for babies to calm down
Design features (clinical trial / retrospective study / case) sample size, determination of the number of centers, study duration, *if any* randomization method and its importance Blindness method and its importance, *if any*	This study was planned as a randomized controlled experimental study. Computer-assisted randomization will be used to create groups (https://www.randomizer.org/). To determine the sample size, power analysis was performed using the G* Power (v3. 1.9) program. The power of the study is expressed as 1-β (β = probability of type II error), and in general, studies must have 80% power. According to Cohen's (1988) effect size coefficients; Assuming that the evaluations to be made between two independent groups would have a medium effect size (d = 0.5), it was determined that there should be at least 64 people in each group, according to the calculation made using the t test.
Address of the clinic, laboratory, other medical units and institutions, if any, from cases , processing of data/keeping records, evaluation criteria, quality control and quality assurance	No samples will be taken from the babies forming the sample group.
Statistical method to be applied	The data obtained in the study were compiled using SPSS (Statistical Package for Social Sciences) for Windows 25.0 program. In evaluating the data; Descriptive statistical methods will be used for number, percentage, min-max , mean and standard deviation values. The compliance of the obtained data with normal distribution will be tested. Compliance with normal distribution can be examined with the QQ Plot drawing (Chan , 2003:280-285). In addition, normal distribution of the data used depends on the skewness and kurtosis values being between ±3 (Shao , 2002). In normally distributed data, when comparing quantitative data, independent t test will be applied for the difference between two independent groups, when comparing two dependent stages, dependent t test will be applied, and when comparing more than two dependent stages, analysis of variance in repeated measurements (MIX ANOVA) will be applied and in case of a difference, Bonferroni will be applied to determine the group that makes the difference. will be used. Chi square analysis will be used to test the relationship between categorical variables.

List of publications: at least 2 (copies will be on file)	- Kuller , J. M. (2014). Update on newborn bathing _ newborn oath baby Nursing Reviews , 14(4), 166-170. -Lund, C. , Kuller , J., & Durand , D. J. (2020). Baby's first bath : Changes in skin barrier function after bathing full term _ newborns with water etc liquid baby cleaner . Pediatric Dermatology , 37(1), 115-119. -Ar, I. , & Gözen, D. (2018). Effects of underrunning water bathing oath immersion tub bathing on vital signs of newborn infants : a comparative analysis . Advances in Neonatal Care , 18(6), E3-E12. -Mohamed , SS A. , Faheim , SS, Farg , DSS, & Hassan, HE The relationship between Trunk-to-Head Bathing oath the Traditional Head-to-Trunk Bathing on Newborns ' Outcome . -Johnson, E ., & Hunt , R. (2019). Infant skin care : updates oath recommendations . Current Opinion in Pediatrics , 31(4), 476-481. - Edraki , M ., Paran , M., Montaseri , S., Nejad , MR, & Montaseri , Z. (2014). comparing the effects of swaddled oath conventional bathing methods on body temperature oath crying duration in premature infants : a randomized clinical trial . Journal of caring sciences , 3(2), 83. -Huang , Y. , Zhou , L., Abdillah , H., Hu, B., & Jiang , Y. (2022). Effects of swaddled oath traditional tub bathing on stress oath physiological parameters of preterm infants : A randomized clinical trials in China . Journal of Pediatrics Nursing , 64, e154-e158. -Burdall , O. , Willgress , L., & Goad , N. (2019). Neonatal skin care : developments in care to maintain neonatal barrier function oath prevention of diaper dermatitis . Pediatric dermatology , 36(1), 31-35. -Lund, C. (2016). Bathing oath beyond : current bathing controversies for newborn infants . Advances in Neonatal Care , 16, S13-S20. -LEE, H.K. (2002). effects of sponge bathing on vagal tone oath behavioral responses in premature infants . Journal of clinical nursing , 11(4), 510-519. -Şerbetçi, G. (2019). Determination of postpartum belly and skin care applications (Master's thesis , Istanbul Medipol University Institute of Health Sciences). -Dağ, Y.S. (2017). Examining the effect of bathing and massage on hyperbilirubinemia in newborns (Master's thesis , İnönü University Institute of Health Sciences). -Ceylan, S. S. , & Bolışık , ZB (2022). Baby Bathing in Neonatal Intensive Care Units: Recommendations for Neonatal Nurses. -So , H.S. , You , MA, Mun, JY, Hwang , MJ, Kim, HK, Pyeon , SJ, ... & Chang , BH (2014). Effect of trunk-to-head bathing on physiological responses in newborns . Journal of Obstetric , Gynecologic & Neonatal Nursing , 43(6), 742-751. -Uçar, E. , & Çınar, N. (2016). Newborn's First Bath: When Should It Be Done ? YILDIRIM BEYAZIT UNIVERSITY NURSING E-JOURNAL, 3(1). -Kelly , P.A. , Classen , KA, Crandall , CG, Crenshaw , JT, Schaefer , SA, Wade , DA, ... & Fossee , KR (2018). Effect of timing _ _ first bath on a healthy newborn's temperature . Journal of Obstetric , Gynecologic & Neonatal Nursing , 47(5), 608-619. -Çaka, S. Y ., & Gözen, D. (2018). Effects of swaddled oath traditional tub bathing methods on crying oath physiological responses of newborns .

	journal for Specialists in Pediatric Nursing , 23(1), e12202. -Ceylan, S. S. , & BOLIŞIK, B. (2017). Newborn Stress Scale Examination of Psychometric Properties. Acıbadem University Journal of Health Sciences, (2), 97-103. Relevant sources have been added to the bibliography file.
Summary of findings from studies conducted / supporting information for this study	So et al. in 2014, investigating the effect of trunk-to-head bathing on the body temperature, heart rate and oxygen saturation of newborns compared to traditional head-to-torso bathing, it was found that stable and healthy term newborns bathed from trunk to head had lower body temperature before bathing than those bathed from head to trunk. It has been determined that they return to their temperatures faster (So , HS et al. 2014). In 2014, by Edraki et al., 50 premature babies in the neonatal intensive care unit were divided into two groups, experimental and control, by random distribution method. The babies in the experimental group were washed with the swaddle bath method, and the babies in the control group were washed with the traditional bath method. Body temperature was measured 10 minutes before and 10 minutes after bathing. Babies' faces were filmed during bathing to record their cries. The average temperature loss in newborns bathed with swaddle baths was lower than those bathed with traditional bathing methods. It was found to be significantly less than in newborns . Additionally, it was observed that the duration of crying was significantly less in the experimental group than in the control group. Considering the positive effect of swaddling on maintaining body temperature and reducing stress, it was concluded that it can be used as a suitable bathing method in the NICU (Edraki, M. et al.). Mohamed et al. to compare the effect of trunk-to-head bathing with traditional head- to-trunk bathing on the body temperature, heart rate, and oxygen saturation of newborns , it was found that trunk-to-head bathing had positive effects on newborns' body temperature, heart rate, and oxygen saturation compared to traditional head-to-trunk bathing. (Mohamed , SS A et al. 2018). The results of this limited number of studies are particularly healthy and at term. There are no consistent results regarding the order in which newborns should be bathed. This suggests that there is a need for well-designed randomized controlled studies on this subject. Based on this literature review, this study was planned to determine the effect of bathing applied in two different orders (washing the body first and the head last, and the classical method of washing the whole body starting from the head first) on stress level, physiological parameters and crying duration in term babies.

Publication policy	The research will be carried out in line with universal ethical principles. Parents of babies who meet the sample selection criteria will be interviewed and informed about the purpose and scope of the research, and their written consent will be obtained. Babies of parents who agree to participate in the study and who meet the sample selection criteria will be included in the study . The information obtained from the research will be used only as research data, the personal information of the baby and its parents will never be included, and confidentiality rules will be strictly followed.