December 1, 2021

Study Protocol

Official Title: The Impact of Different Skin Suture Methods in Episiotomy Repair on Healing and Pain: A Randomized Clinical Trial

NCT06379048

This randomized clinical trial is planned to be conducted at Başakşehir Çam and Sakura City Hospital, a tertiary care center in İstanbul, Türkiye, between March and August 2022, to compare three skin closure techniques—mattress (M-Suture), simple interrupted (I-Suture), and subcutaneous continuous (SC-Suture)—used in episiotomy repair among primiparous women aged 18–45 who underwent vaginal delivery with episiotomy. Patients are planned to be randomly assigned to groups using a computer-generated stratified block design (blocks of 3, 6, and 8), with allocation revealed just before the procedure. Exclusion criteria include multiple births, deep vaginal lacerations, fetal anomalies, operative delivery, coagulopathy, and lateral lacerations. A standardized mediolateral episiotomy and repair technique is planned to be used across groups, and visual models is planned to be employed to ethically standardize the novel suturing approaches. Pain and healing are planned to be assessed using the REEDA and Visual Analog Scale (VAS) scores on postpartum days 1 and 15. Statistical analyses are planned to be conducted using SPSS v23, with ANOVA for group comparisons and significance set at $p<.05$. The study is planned with a sample size of 132 to ensure 80% power at a 5% significance level, accounting for a 10% attrition rate.