IRB Number: Pro00111100
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Study Title: Transcutaneous electric nerve stimulation for analgesia during outpatient endometrial biopsy: a randomized controlled trial (TENS RCT)
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Study Location: Duke University
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We plan to conduct a superiority trial. Prior research has established that a 25-30% reduction in overall pain or a 13-15 mm decrease in VAS represent clinically significant differences in pain scores. We determined a standard deviation of 30 mm as based on a prior similar study by Yilmazer et al. We will conservatively plan for a sample size sufficient to detect a 15 mm reduction in pain scores in the intervention group as compared to the control group. We would need 64 subjects in each group for a total of 128 subjects to attain 80% power at alpha = 0.05 level of significance, which corresponds to a Cohen's d around 0.50 (moderate reduction). We hope to recruit 160 participants for this trial to account for an assumed attrition rate of 20%.

Data will be recorded using Research Electronic Data Capture (REDCap). Pain will be measured along discrete intervals including: speculum placement, tenaculum placement, immediately after biopsy, removal of speculum, 5 minutes after biopsy and 15 minutes after biopsy. The primary outcome will be pain score immediately after biopsy. The primary outcome will be compared between treatment arms using linear regression adjusting for baseline pain. Secondary outcomes include pain score at other intervals, patient tolerability and acceptability, and provider's satisfaction with the procedure. All testing will be performed at a two-tailed significance level of 0.05.

As there is no standard analgesia option, patients may be offered pain medication prior to the procedure such as ibuprofen. While this would not be a contraindication to enrollment, we anticipate adequate block randomization for this to normalize in both groups, and we will note what form of analgesia was used during our statistical analysis. We believe there is an important value to allow providers to continue their normal standard of care options.