Negative Pressure Wound Therapy-PICO: Cosmesis in Repeat Cesarean Section

Device: PICO-7 Negative Pressure Wound Pump

NCT # 05266053

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Statistical Analysis:

We plan to enroll approximately 100 women with a previous C-section, which will be randomized 1:1 to either the standard dressing or PICO 7 dressing. The primary outcome will be the patient component of the Patient and Observer Scar Assessment Scale (POSAS) assessed at 2 weeks, 4 weeks, and 6 weeks following C-section. The primary time point of interest will be at 6 weeks since we expect the most improvement will be seen at the later time point. If approximately 20% drop-out by 6 weeks, then with N = 80 (40 per group), we will have 80% power to detect a .7 SD difference in mean scar assessment at 6 weeks between the two-groups using a two-sample t-test with equal variance and type I error set at 0.05 which provides conservative power compared to our linear mixed model. Based on a small RCT pilot study for C-section scars which used this instrument (Ekin et al., 2018), the effect sizes for the Patient, Observer, and Total POSAS were ES = 1.18, 1.03, and 1.15, respectively. Also, the pooled SD was 7.2 for the Patient version, thus assuming our population will have a similar SD in this measure; we will be able to detect approximately a 5-point change (0.7 x 7.2) in Patient POSAS. Thus, we should have adequate power to detect meaningful improvements in scar assessment.