Evaluation of Objective Pain Measurement Device

NCT03975660

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Statistical Analysis Plan

The correlation coefficient will be calculated between patients' subjective pain ratings (NRS) and the calculated ROPA scores. Receiver operating characteristic (ROC) curves will be generated to evaluate the ability of the ROPA system to distinguish between clinically significant pain cut-off values representing no/mild, moderate, and severe pain, and area-under-the-curve (AUC) will be calculated. The comparisons performed during this analysis included the following clinically relevant cutoffs: no/mild pain (NRS ≤ 3) vs. moderate-severe pain (NRS >3); no/mild/moderate pain (NRS ≤ 6) vs. severe pain (NRS > 6); and no/mild pain (NRS ≤ 3) vs. severe pain (NRS > 6). Prior to study initiation, performance thresholds were deemed to represent either good (70-79%), very good (80-89%) or excellent (> 90%) performance in terms of AUC. Finally, the correlation coefficient between the NRS and ROPA will be calculated.