Statistical Analysis Plan

Trauma-PC^2: Treatment of Adult Traumatic Rib Fractions With Percutaneous Cryoneurolysis for Pain Control

NCT: NCT05330611

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1 Timeline

Enrollment begins January 2023.

An interim analysis will be completed when 20 patients have been enrolled.

2 Enrollment & sample size

Forty (40) patients will be enrolled: 20 will receive the intervention and 20 will receive standard of care.

Using a two-sample t-test with 5% significance, 80% statistical power, and assuming a standard deviation of 2 in pain scores (based on the pooled standard deviation of pain scores among the first 50% of enrolled EPERC patients), a 20% difference in mean pain scores between SOC and treatment patients can be identified with a total of 34 patients (17 in each group). Accounting for 15% attrition (which we believe to be on the high end due to 1) the short duration between enrollment and the primary outcome and 2) the fact that at the 50% enrollment mark of the EPERC trial, only 1 of the 59 patients did not have the primary outcome available), we will enroll a total of 40 patients.

3 Primary outcome

The primary outcome is the difference in mean numeric pain score at discharge (SOC minus treatment) and will be evaluated through a two-sample t-test. A p-value and 95% confidence interval will be provided.

4 Secondary outcomes

Secondary outcomes include length of hospital stay, daily narcotic equivalents at discharge and 30-days, 30-day mortality, need for ICU admission, 30-day rib-specific readmission, and long-term pain and quality of life as measured by GOS-E and SF-12 scores at 30, 90 and 365 days.

Length of hospital stay will be analyzed with a generalized linear model with poisson distribution (a negative binomial distribution will be considered if there is overdispersion).

Daily narcotic equivalents at discharge and 30 days will be compared using a two-sample t-test.

Thirty-day mortality will be compared as the difference in proportions, with 95% confidence intervals for the difference calculated with the Wald method. Similarly, for need for ICU admission, and 30-day rib-specific readmission.

GOS-E and SF-12 (PCS and MCS) scores over time (30, 90, and 365 days) will be evaluated using mixed effects generalized linear models.

These outcomes will be evaluated and presented in the final analysis report with 95% confidence intervals. As this is a pilot study, p-values will not be provided.

5 Interim analysis

At 50% enrollment (N=20 patients), an interim report will be provided. This report will include *only* baseline information. No outcomes (primary or secondary) will be included in the interim report.

6 Final analysis

After enrollment has reached 100%, a final analysis report will be created. This report will include baseline information by treatment group, a treatment comparison of the primary outcome with corresponding 95% confidence interval and p-value, and secondary outcomes with corresponding 95% confidence intervals.