Topical Capsaicin Cream for Treatment of Suspected Cyclical Vomiting Syndromes

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Statistical Analysis Plan

Assuming a clinically meaningful effect size of 3 cm difference in the nausea VAS (primary outcome) between capsaicin and placebo groups and standard deviation of 2.5 cm, we estimate that we would require 12 subjects in each of two groups to allow for 80% power and alpha 0.05. To account for imprecision in the effect size and the unknown factor of early treatment withdrawal due to skin irritation, we planned a total sample size of 30 participants.

We evaluated baseline characteristics of the overall cohort using descriptive statistics and report discrete data as frequencies and percentages and continuous data as medians and interquartile ranges. For all outcomes, we used intention-to-treat analysis. For one patient in the capsaicin group, the nausea VAS at 30 and 60 minutes was missing; we used multiple imputation to assign these values. Analysis included Chi-square test or Fisher's exact test for unadjusted comparisons of categorical outcomes between treatment groups. Analysis also included student's t-test, or Mann-Whitney U test, as appropriate for unadjusted comparisons of continuous variables between treatment groups. A p-value <0.05 (two-tailed) was considered statistically significant for all tests. We performed all analyses using SAS 9.4 (Cary, NC) and report primary results with 95% confidence intervals (CI).