A pilot randomized trial of oral magnesium supplementation on supraventricular arrhythmias

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Statistical analysis

The goal of the pilot study was to assess adherence to the Mg supplement, and feasibility of using the ZioPatch and collect preliminary data on PACs, a predictor of AF. The targeted sample size of 60 was determined to detect a difference in the change in log PACs (follow-up minus baseline) between treatment groups of 0.79 standard deviation units with 80% power and 5% type I error (2-sided), assuming 5 participants would not complete follow-up.

All analyses were intent-to-treat. Descriptive statistics are provided according to treatment assignment for baseline characteristics, adherence, Mg concentrations and other outcomes. Differences in baseline characteristics between groups were assessed using t-tests for continuous variables and Fisher's exact tests for categorical variables. Linear regression was used to evaluate whether change in outcomes differed according to treatment assignment, adjusting for the randomization stratification factor (age ≥65 vs <65) and baseline value of the outcome with robust variance estimates for confidence intervals and P-values. Post-hoc sensitivity analyses further adjusted for sex. As PAC burden is highly skewed, we pre-specified using log PAC burden for analysis and reported the ratio of geometric means. Pre-specified subgroup analyses were also performed, stratified by baseline magnesium concentration (< vs. ≥ median). A 2-sided p-value of <0.05 was used to indicate statistical significance. Analyses were conducted using R