Statistical Analysis Plan

Title of Study: Management of Persistent Epistaxis Using Floseal Hemostatic Matrix

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Sample Size:

An *a priori* sample size was calculated using a non-inferiority limit (d) set at 25%, significance level (α) of 5% and power of 80%. We assumed that success in each group will be approximately 93% based on the literature examining anterior nasal packing in ideal conditions and considering our selection criteria in the Floseal® (Baxter, USA) population. Attrition will be assumed to be 0% due to the short duration of treatment. This should yield 26 participants with 13 patients in each study arm.

Statistical Analysis of Clinical End-points:

This is a non-inferiority trial. A non-inferiority design was chosen due to the anticipated improvement in patient comfort and potential decreased cost thus making the experimental arm a preferred option if non-inferiority can be demonstrated in terms of hemostasis. Further, based on existing literature we do not anticipate a significant difference in terms of efficacy between these two groups. All dichotomous categorical variables will be analyzed by means of the Fisher's exact test. Mean age, CCI and VAS pain scores will be compared using the non- parametric Mann-Whitney U Test.