Statistical Analysis Plan (SAP)

CYN13-PICOREVLITE

PICOSURE Alexandrite Laser AND REVLITE Nd:Yag Laser FOR THE TREATMENT OF UNWANTED TATTOOS

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PicoRev Sample Size Rationale

The primary objectives of this study include establishing treatment parameters, assessing safety of the treatment, and comparison of the PicoSure laser to the RevLite laser. Due to the wide variety of treatment parameters to be assessed it was decided to outline up to 10 different treatment subgroups to help further identify subjects based on subject demographics, tattoo characteristics, and additional parameters that may need to be established but are not currently identified. If we assume we a treatment effect of a score of 2 on the tattoo clearance grading (0-3) which corresponds to 50% identifies a treatment effect, with a set power of 95% and a two sided significance level of 0.05, it results in a required study population of 6 subjects for each treatment subgroup. To account for subjects withdrawing or potential lost-to-follow ups due to the extended timeframe of up to 10 treatments every six weeks, it was decided to enroll up to 10 subjects in each group. With a potential of 10 total groups, it is determined that up to 100 subjects may be enrolled in the study.