



**JOHNS HOPKINS**  
M E D I C I N E

# **Fractional laser assisted steroid therapy vs intralesional steroids in the treatment of keloids**

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**PI: Ginette Okoye, MD**

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## **CTReP Derm: #150**

**Cutaneous Translational Research Program (CTReP)**

**Johns Hopkins Outpatient Center, Room 8033C**

**Department of Dermatology**

**(410) 502-SKIN**

### ***Statistical Plan***

The differences in baseline scores between the two keloids within an individual will be assessed using the Wilcoxon signed-ranks test. For each treatment regimen, mean differences in scores at follow-up visits relative to the baseline visit will be calculated using generalized estimating equations, specifying an independent correlation structure to account for multiple visits within an individual over time. We will estimate 95% bootstrap confidence intervals by generating standard error estimates based on 1000 bootstrapped replicates. The p-value for trend will be calculated by treating the categorical visit number as continuous in the regression model. The difference in the effectiveness of intralesional kenalog with CO<sub>2</sub> laser versus intralesional kenalog alone in decreasing mean outcome scores over time will be computed using interaction analyses. The p-value for interaction will be calculated by adding a cross-product term of the categorical visit number and treatment regimen variables into the regression model and conducting a Wald test. Given the paired study design, in instances in which an outcome score was missing at a specific visit for one treatment group, the score corresponding to the other treatment group will also be excluded from the analysis to maintain comparability in paired and stratified analyses. Otherwise analyses will be conducted using all available data. We will conduct a sensitivity analysis in which individuals with a missing data point at any visit for a specific outcome measure will be excluded in the analysis for that outcome measure. All statistical analyses will be conducted using Stata 14.0 (StataCorp, College Station, TX).