

**Title:** Does early platelet rich plasma injection decrease the risk of post-traumatic arthritis in pilon fractures undergoing two-staged open reduction with internal fixation?

**Date:** 08/30/2016

**Principal Investigator:** Brett Crist, MD

**NCT:** 02481869

## **Sample Size Determination**

Number of patients per group was determined from a pre-study power analysis using previously published data on prevalence of PTA after pilon fracture – the assumption being that a 10% reduction in percentage of patients experiencing symptomatic PTA would be clinically significant.

## **Data Analysis**

For data analysis, PTA presence will be defined based on a diagnosis of OA, or findings consistent with OA, reported for either imaging modality at any assessment time point. PTA severity will be determined from whole-joint MRI scoring and patient reported outcomes at 18 months after surgery and categorized as mild, moderate or severe. To test the first hypothesis, we will compare treatment groups for statistically significant ( $p < 0.05$ ) differences in proportions with PTA, proportions within each severity category, and PRO scores using Fisher's exact tests, t-Tests, and rank sum tests. To test the second hypothesis, we will perform receiver operator characteristic curve analyses to determine the discriminatory capabilities (area under the curve (AUC)) of the panel for distinguishing the presence and severity of PTA. The injured ankle will be compared to the normal, contralateral ankle and  $AUC > 0.8$  will be considered to represent high and clinically useful discriminatory capability. In addition, patient age, gender, BMI, tobacco use, and co-morbidities, as well as the pre-operative CT scan injury severity score<sup>11</sup> will be assessed as variables for predicting likelihood of presence and severity of PTA using Fisher's exact test and odd's ratios.