

Official Title: Effects of Metformin on Low Back Pain

ClinicalTrials.gov ID (NCT number): NCT04055012

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Statistical Analysis Plan

The primary outcome is change in pain score and disability score between baseline and 12 months, using the minimal clinically meaningful change. Sample size was estimated based on feasibility of subject recruitment based on prior study of axial low back pain, as well as prior studies demonstrating clinically and statistically significant change in the primary outcome of NPRS. However, given the early termination of the study prior to reaching an adequate sample size, outcome measures are reported with descriptive statistics only, ie. mean and standard deviation, with insufficient numbers to permit formal between group comparisons.