

**Study Title: Buprenorphine/Naloxone Stabilization and Induction onto Injection Naltrexone**

Principal Investigator: Adam Bisaga, MD

ID: 6999

NCT02294253

August 13, 2018

**Statistical Analysis:**

This is a single-arm, open-label, pilot study evaluating whether individuals with opioid use disorder who were unable to tolerate a rapid transition to XR-naltrexone would tolerate a slow four-week buprenorphine taper and XR- naltrexone induction.

Study objective was to evaluate the feasibility of the slow-transition protocol and to obtain descriptive data regarding baseline demographics and treatment outcomes in such patients.

Analytical plan include: 1) percent of participant who completed the transition, 2) time to relapse defined as daily opioid use for 5 days or study dropout, and 3) descriptive statistics on baseline characteristics comparing participants who successfully initiated XR-NTX and those who did not initiate XR-NTX. Summary statistics will include frequency, percentages, and where relevant averages.