

Statistical analysis plan

The results of the study will be analysed using the ITT (Intention-to-treat) approach. Primary null hypothesis: the proportion of patients with treatment success is the same in the control and active phase. When assuming 15% success rate in the control phase and 50% success rate in the active phase, we need 40 patients for 80% power to show that the success rate in the active phase is statistically significantly higher at the alpha level 5% (using a two-sided Fisher's exact test) while accounting for 20% drop out rate.