

Use of Ultrasound Guidance to Assist with Labor Epidural Placement in Patients with a BMI \geq 40

NCT02984267

Date: 10/1/2016

Statistical analysis plan

The primary outcome is total time (minutes) to successful epidural catheter placement, defined as the sum of the ultrasound or palpation time, plus the epidural catheter placement time. The present study focused on the morbidly obese population ($\text{BMI} \geq 40$), of which we are unaware of any available data to guide a calculation for the primary outcome. Based on pilot data means and variances, total sample size will be calculated with 80% power to detect a six-minute difference in time-to-placement between groups with an alpha of 0.05 (two-tailed).

Distribution normality of continuous data will be examined using box plots and histograms. Non-normally distributed data will be compared using the Kruskal-Wallis H test, and continuous data compared with the Mann-Whitney U test. Normally distributed continuous variables will be compared using the independent sample Student t-test. The Fisher Exact test will be used for categorical variables. A P-value of ≤ 0.05 will be considered statistically significant.