

Title of the study: Effects of Glucagon-Like Peptide-1 Agonists on Metabolism and Ectopic Fat Deposition in Chronic Kidney Disease: A Pilot and Feasibility Study

NCT number: NCT05254418

Date: 12/02/2024

Statistical Considerations

Sample size

Up to ten subjects will be enrolled to participate in the study. This study design will provide preliminary data on the effects of GLP-1RA on ectopic fat deposition, mitochondrial function, and physical performance in patients with CKD. We performed a power analysis based on the study by Neeland et al, investigating the effects of liraglutide on VAT in overweight and obese patients. According to their results, liraglutide treatment for a median of 36 weeks results in a mean change in VAT of 12.49%, with a standard deviation of 9.3%. Using their findings, we estimated the power for detecting changes in VAT based on a sample size of 10 using paired-t test (Figure 10.1). For a sample size of 10, there is adequate power to detect a mean change of 9% or more in VAT with a standard deviation of 9% and alpha value of 0.05.

Figure shows how the power would change if the sample size were to be extended to 20 following the pilot study.

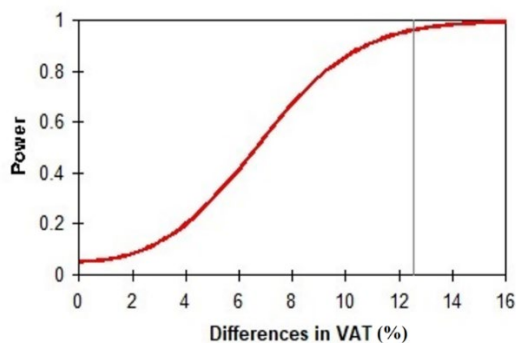


Figure 10.1

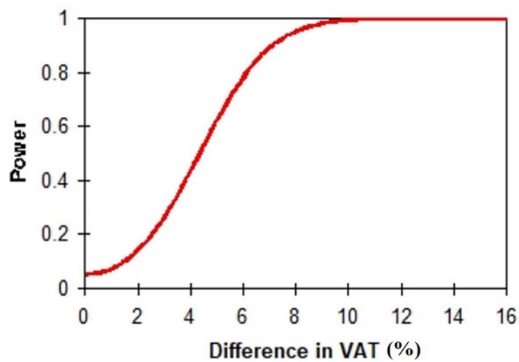


Figure 10.2

Data Analysis

The comparison of primary and secondary outcomes, specifically the differences in (a) intermuscular fat deposition, (b) adipose tissue insulin resistance, (c) peripheral insulin resistance, (d) visceral tissue fat deposition, (e) phosphocreatine recovery time constant, (f) physical performance score, before and after dulaglutide administration will be assessed using Wilcoxon signed-rank tests.

Generalized linear mixed effects models will be used to examine associations of GLP-1RA with changes in outcomes with more than 2 repeated assessments. All p-values will be two-tailed ($\alpha=0.05$) and analyses will be completed using Stata 16.