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Title: Vitamin D and Residual Beta-Cell Function in Type 1 Diabetes

ClinicalTrials.gov Identifier: NCT03046927

STATISTICAL PLAN AS DETAILED IN THE RESARCH STRATEGY OF THE FUNDED GRANT
Grant ID: 1 R21 DK113353-03

DATED 5/30/2016

STATISTICAL CONSIDERATIONS: All analyses will be overseen by Dr. Bruce A. Barton, Professor of Biostatistics at UMMS, and performed by analysts at the Quantitative Methods Core.
Sample Size and Power Calculation: This trial's sample size was based on establishing a stable estimate (with a 95% confidence interval) for the difference in C-peptide between the two treatment groups. Based on published data[27], group sample sizes of 13 in each arm, will produce a two-sided 95% confidence interval with a distance from the difference in means to the limits of 0.081 nmol/l when the estimated standard deviation is 0.10 in each group; i.e., if the estimated difference in C-peptide between the two treatment groups is 0.12 nmol/L, the 95% confidence interval will be ± 0.081. Recruitment goal was increased from 40 to 48 on 6/10/2019 to enable further analysis by BMI strata and to compensate for attrition.
Statistical Analysis: For this trial, PCR will be defined by IDAA1C, a new two-dimensional definition that is clinically meaningful as it relates insulin dose and measured HbA1c to the residual β-cell function[4]. When compared to previous definitions, IDAA1C gave the best agreement with stimulated C-peptide definition of >300 pmol/L[28]. The formula for IDAA1C is as follows: HbA1c (%) + [4 X insulin dose (units/kg/24h)]. PCR is defined as IDAA1C of ≤9[4]. Initially, we will use analysis of covariance (ANCOVA) to analyze the primary (and secondary) outcome of change from baseline at 12 months as predicted by treatment group assignment and adjusted for the baseline measure. We will follow intention to treat principles in our initial analyses. Further analysis will use a mixed effects model approach to include measures at all time points during the study.