

Study Statistical Analysis

Official Title: Zoledronic Acid for Osteoporotic Fracture Prevention (ZEST II)

ClinicalTrials.gov ID (NCT number): NCT02589600

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All statistical analyses will use SAS® version 9 (SAS Institute, Inc., Cary, North Carolina) based on intention-to-treat. First, appropriate descriptive statistics will be computed and graphical summarizations made for all variables for each treatment group for each time point as well as raw and percent change scores from baseline to obtain an overall sense of the distributional characteristics, missing values and general data quality. Second, baseline measures will be compared across arms using independent samples t- and a Wilcoxon rank sum tests, as appropriate, for continuous variables and chi-square and Fisher's exact tests, as appropriate, for categorical variables. Although no significant differences are expected due to randomization and large sample size, any variables found to be significantly different will be accounted for by including them as covariates in sensitivity analyses. Third, main analyses will be performed using a negative binomial regression model. Finally, exploratory analyses will be performed.