



Pen Bay Medical Center
MaineHealth

Official Title: ATIVO Study – Anticoagulation Therapy in the Very Old

NCT #: 03103763

Statistical analysis plan

For the purpose of this study, we attempted to detect differences in outcomes among age groups (70-79, 80-89, and 90+) undergoing anticoagulation therapy at study enrollment and in 6-month intervals for 24 months. Descriptive statistics were used to summarize the demographic (age group, sex, and living arrangement) and clinical characteristics (mobility, alcohol use, CHADS2-VASc, Fragility score, mini Cog, and mobility scale) of patients included in the study, with continuous variables presented as a mean +/- standard deviation and categorical variables as frequencies/percentages of the total. The primary outcome of interest was time in therapeutic range (TTR), a percentage of time that a patient's International Normalized Ratio (INR) values were in range over a 6-month period. Secondary outcomes were all-cause mortality, stroke, and major bleeding events. Student t tests and chi-squared tests were conducted to compare data between groups. Statistical significance was set at $P < .05$ with a 95% confidence interval.