

Randomization to Letrozole vs. Anastrozole in Short Pubertal Males

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Statistical Methods

Baseline auxologic and hormonal measures were summarized by treatment arm. Laboratory measures over time were presented as means with standard deviation, with key measures (total testosterone, estradiol, IGF-1) additionally displayed as boxplots by arm. Growth velocity (cm/year), height (cm), bone age (months), predicted adult height (cm), and DEXA z-scores over time were similarly visualized. Adverse events were listed by arm, and spinal film was assessed qualitatively.

To include all patients in an intent-to-treat approach, mixed effects linear regression was used to model each outcome as a function of treatment arm, indicators for follow-up timepoints, and their interaction for assessing effect modification of annual change by arm. Within-patient correlation was accounted for by a random effect. Estimated change since baseline with 95% confidence intervals were presented by arm if effect modification was deemed significant at the 0.05 alpha level and as an overall effect otherwise. All analyses were performed in the R statistical computing framework, version 4.0¹.

¹ R Core Team (2020). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL <https://www.R-project.org/>