Long-term safety and efficacy of guanfacine extended release in children and adolescents with ADHD.

Huss M, Dirks B, Gu J, Robertson B, Newcorn JH, Ramos-Quiroga JA.

Eur Child Adolesc Psychiatry. 2018 Feb 13.
doi: 10.1007/s00787-018-1113-4.

Abstract

Data are reported from SPD503-318, a phase 3, open-label, safety study of guanfacine extended release (GXR) in European children and adolescents with attention-deficit/hyperactivity disorder (ADHD). Participants received dose-optimized GXR (1-7 mg/day) for up to 2 years. Of 215 enrolled participants, 214 were included in the safety population and 133 completed the study. Participants' mean age was 11.7 years and 73.8% were male. Overall, 177 participants (82.7%) experienced a treatment-emergent adverse event (TEAE). TEAEs reported in at least 10% of participants were somnolence (36.0%), headache (28.5%), fatigue (20.1%), and nasopharyngitis (11.7%). Serious TEAEs were reported in 4.7% of participants and TEAEs leading to discontinuation were reported in 3.3% of participants. There were no deaths. Mean z-scores for BMI were stable throughout the study. The incidence of sedative TEAEs (somnolence, sedation, and hypersomnia) peaked during week 3 and decreased thereafter. Small changes from baseline to the final assessment in mean supine pulse [- 5.5 bpm (standard deviation, 12.98)] and blood pressure [systolic, 0.6 mmHg (9.32); diastolic, 0.2 mmHg (9.17)] were reported. ADHD symptoms initially decreased and remained significantly lower than baseline at study endpoint. At the final assessment, the mean change in ADHD-RS-IV total score from baseline was - 19.8 (standard error of mean, 0.84; nominal $p < 0.0001$). In conclusion, GXR was well tolerated and more than 60% of participants completed the 2-year study.