OBJECTIVE:
An extended-release amphetamine (AMP) oral suspension has been developed to facilitate medication ingestion and dose titration. This study sought to determine the pharmacokinetic (PK) profile of this new formulation in children with attention-deficit/hyperactivity disorder (ADHD).

METHODS:
This was an open-label, single-period, PK study in 29 pediatric participants with ADHD. Participants were stratified into age groups 1 (6-7 years), 2 (8-9 years), and 3 (10-12 years), and dosed with 15 mL extended-release AMP liquid suspension (equivalent to 30 mg mixed AMP salts) after an overnight fast. Blood samples were collected at prespecified time points and analyzed for d- and l-AMP concentrations. Key PK parameters included maximum plasma concentration (Cmax), time to maximum plasma concentration, half-life (T1/2), area under the curve from time 0 to last quantifiable concentration (AUCLast) and to infinity (AUClinf), oral clearance (CL/F), and volume of distribution (Vz/F). The 95% confidence intervals (CIs) about the geometric means of the weight-normalized CL/F/kg and Vz/F/kg were within the 60%-140% range for groups 2 and 3, while those of weight-normalized AUCLast were within range for all age groups. Adverse events were mild and consistent with the safety profile of AMP.

RESULTS:
All participants completed the study. As age increased, mean maximum and total exposure to AMP decreased; weight-normalized CL/F slightly increased, resulting in decreasing T1/2 values with age. For d- and l-AMP, the 95% CIs for the geometric means of weight-normalized CL/F/kg and Vz/F/kg were within the 60%-140% range for groups 2 and 3, while those of weight-normalized AUCLast were within range for all age groups. Adverse events were mild and consistent with the safety profile of AMP.

CONCLUSIONS:
Exposure (Cmax, AUClinf, and AUCLast) to AMP decreased with age, possibly as a result of the 30-mg/15-mL fixed dose across a range of weights (20-57 kg) and the consequent lower dose per kilogram in older participants, as well as the slight increase in clearance with age.