

Clinical Trial for individuals diagnosed with Tuberous Sclerosis Complex (TSC) who are between the ages of 6-21 with an IQ greater than or equal to 60

We are currently conducting a clinical trial at Children's Hospital Boston for individuals diagnosed with TSC between the ages of 6-21 years and with an IQ greater than or equal to 60. The goal of this study is to investigate if the study drug affects learning skills (neurocognition) in individuals diagnosed with TSC. The trial involves Children's Hospital Boston and Cincinnati Children's Hospital Medical Center and is sponsored by a pharmaceutical company named Novartis and the Tuberous Sclerosis Alliance.

If you/your child qualifies for the treatment phase of the trial after initial screening tests, you/your child would be asked to take by mouth either the study drug or a placebo (inactive drug), which is determined by chance.

The study involves about 9 visits to Children's Hospital Boston over a six month timeframe. The study visits include blood draws, laboratory tests and other screening evaluations such as neuropsychological, seizure and sleep assessments. The study drug will be provided at no charge, and a voucher for parking will be provided to you at each study visit.

We hope that the knowledge we gain from investigating this study drug will improve the treatment of individuals with TSC, and that future patients may benefit from what is learned.

If you are interested in participating in this trial, please contact Melanie Jacobs at (617) 919-3499 or melanie.jacobs@childrens.harvard.edu.