RESEARCH PLAN FOR A CASE REPORT OF D-LYXO-HEXULOSE TREATMENT IN AN INFANT WITH PRADER-WILLI SYNDROME

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Prader-Willi Syndrome is a complex genetic disorder involving a dysfunctional hypothalamic- pituitary axis and has an estimated prevalence of 1/15,000, which is equivalent to 40,000 affected individuals in the United States. The symptoms of Prader-Willi Syndrome include hypotonia, hypogonadism, impaired intellectual development, short stature, and excessive hyperphagia leading to severe obesity. Patients with Prader-Willi Syndrome have a six-fold increased risk of premature death compared to healthy controls, most often due to obesity-related complications. Although treatment with recombinant human growth hormone shows beneficial effects on many of the symptoms of Prader-Willi Syndrome, the excessive hunger and resulting development of obesity remain unaffected. To fulfill this unmet need, we have submitted an application for orphan drug designation for D-lyxo-hexulose to treat Prader-Willi Syndrome. D-lyxo-hexulose is a C4 epimer of fructose with comparable sweetness to sucrose, and has regulatory approval for use as a food additive. It has previously shown beneficial effects on satiety in clinical studies with healthy individuals and weight loss in clinical studies with Type 2 Diabetes Mellitus patients, but its effects on satiety and weight loss have not yet been evaluated in Prader-Willi Syndrome. Thus, we are preparing to conduct an exploratory case study for the efficacy of D-lyxo-hexulose treatment in an infant with Prader-Willi syndrome. The results of this case study will be used in the future to support the approval of orphan drug status for D-lyxo-hexulose in Prader-Willi Syndrome and a larger subsequent clinical trial.

Utility of the CAARS Validity Scales in Identifying Feigned ADHD, Random Responding, and Genuine ADHD

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Objective: Due to recent concern about malingered self-report of symptoms of attention- deficit/hyperactivity disorder (ADHD) in college students, there is an urgent need for scales that can detect feigning of this disorder. The present study provided further validation data for a recently developed validity scale for the Conners' Adult ADHD Rating Scale (CAARS), the CAARS Infrequency Index (CII), as well as for the Inconsistency Index (INC).

Participants and Methods: A total of 139 undergraduate students completed the CAARS; 21 individuals with diagnoses of ADHD, 29 individuals responding honestly, 54 individuals responding randomly to either all or half of the CAARS items, and 35 individuals instructed to malinger ADHD while avoiding detection. A financial incentive of $25 was offered for successful feigning.

Results: Overall, the INC showed moderate sensitivity to random responding (.44-.63) and fairly high specificity to ADHD (.86 -.91). The CII demonstrated modest sensitivity to malingered ADHD (.31-.46) and excellent specificity to genuine ADHD (.91 -.95). Sequential application of validity scales had correct classification rates for honest (93.1%), ADHD (81.0%), malingering (57.1%), half random (42.3%), and full random (92.9%). Of note, the INC and CII flagged more malingerers as invalid when applied in a stepwise manner (57.1%), as opposed to when using the CII alone (34.3%).

Conclusions: Although the present study demonstrated modest sensitivity in the detection of feigning, the fact that 43-69% of malingerers went undetected suggests the need for more research. This study has added to the literature by demonstrating the utility of the CAARS validity scales working together to distinguish between various response sets. Finally, if using the algorithm clinically, clinicians should have strong specificity and at least modest sensitivity in the detection of feigning on the CAARS, provided results are successfully cross-validated.