

Statistical Analysis Plan

Identifiers: NCT02189213

Protocol ID: 6884

Title: Treatment of Pediatric Anxiety Disorders by Predicting Treatment Response Through Biocellular Markers and Sleep Module

PI: Amir Levine

Date: 08/30/2021

Introduction

Background

Anxiety disorders are among the most common and debilitating psychiatric conditions in youth, affecting more than 10% of all children and adolescents. Selective-serotonin reuptake inhibitors (SSRIs)—the first-line psychopharmacologic treatment for pediatric anxiety disorders—produce benefit in only 50-60% of patients and can take up to 12 weeks to improve symptoms.

Study Design

METHODS

We conducted a prospective, open-label trial of flexibly-dosed sertraline in children and adolescents with generalized, separation and or social anxiety disorders.

Aims and Objectives

To measure improvement after treatment with sertraline using the Clinical Global Impressions Improvement (CGI-I) Scale

Hypothesis: At least 50% of subjects will respond to Sertraline treatment (CGI-I greater than or equal to 2).

Outcomes

Primary outcomes

The primary outcome in the study was response to sertraline measured by the Clinical Global Impressions Improvement (CGI-I) Scale.

Response to Sertraline was defined as The Clinical Global Impressions Scale Clinical Global Impressions Improvement (CGI-I) Scale, an instrument used to quantify and track patient progress and treatment response over time.

The CGI was developed for use in NIMH-sponsored clinical trials to provide a brief, stand-alone assessment of the clinician's view of the patient's global functioning prior to and after initiating a study medication.¹ The CGI provides an overall clinician-determined summary measure that takes into account all available information, including a knowledge of the patient's history, psychosocial circumstances, symptoms, behavior, and the impact of the symptoms on the patient's ability to function.

The CGI-Improvement scale comprises a one-item measures evaluating the following change from the initiation of treatment on a seven-point scale.

The following one query is rated on a seven-point scale: “Compared to the patient's condition at admission to the project [prior to medication initiation], this patient's condition is: 1=very much improved since the initiation of treatment; 2=much improved; 3=minimally improved; 4=no

change from baseline (the initiation of treatment); 5=minimally worse; 6= much worse; 7=very much worse since the initiation of treatment.

CGI-I scale of 1-2 is considered response to treatment. Anything below that (3-7) is considered non-response to sertraline treatment.

Analyses

RESULTS

7 patients completed the trial. Out of the 7 three were non-responders CGI-I less than 2, and 4 were responders, CGI-I score equal to or greater than 2 two-tail t-test was performed.

Safety outcomes

There were no serious adverse events.