NIAAA Data Access Application

NCIG 006 - A Randomized, Double-Blind, Placebo-Controlled Trial of the Safety and Efficacy of HORIZANT® (Gabapentin Enacarbil) Extended-Release Tablets for the Treatment of Alcohol Use Disorder

Title of Research Project:

Introduction

The purpose of this study was to conduct a large, multisite clinical trial of gabapentin enacarbil extended-release (GE- XR) (HORIZANT®), a gabapentin prodrug formulation, to determine its safety and efficacy in treating alcohol use disorder (AUD). Men and women (n = 346) who met DSM-5 criteria for at least moderate AUD were recruited across 10 U.S. clinical sites. Participants received double-blind GE-XR (600 mg twice a day) or placebo and a computerized behavioral intervention (Take Control) for 6 months. Efficacy analyses were prespecified for the last 4 weeks of the treatment period. The GE-XR and placebo groups did not differ significantly on the primary outcome measure, percentage of subjects with no heavy drinking days (28.3 vs. 21.5, respectively, p = 0.157). Similarly, no clinical benefit was found for other drinking measures (percent subjects abstinent, percent days abstinent, percent heavy drinking days, drinks per week, drinks per drinking day), alcohol craving, alcohol-related consequences, sleep problems, smoking, and depression/anxiety symptoms. Common side-effects were fatigue, dizziness, and somnolence. A population pharmacokinetics analysis revealed that patients had lower gabapentin exposure levels compared with those in other studies using a similar dose but for other indications. Overall, GE- XR at 600 mg twice a day did not reduce alcohol consumption or craving in individuals with AUD.

The study sponsor was the National Institute on Alcohol Abuse and Alcoholism's (NIAAA) Clinical Investigations Group (NCIG). The data set was prepared by NIAAA and FastTrack Drugs and Biologics (the trial's Coordinating Center) and was reviewed by CSR Incorporated.

A more detailed overview of the study and main results can be found in the primary publication:

Falk DE, Ryan ML, Fertig JB, Devine EG, Cruz R, Brown ES, Burns H, Salloum IM, Newport DJ, Mendelson J, Galloway G, Kampman K, Brooks C, Green AI, Brunette MF, Rosenthal RN, Dunn KE, Strain EC, Ray L, Shoptaw S, Ait-Daoud Tiouririne N, Gunderson EW, Ransom J, Scott C, Leggio L, Caras S, Mason BJ, Litten RZ; National Institute on Alcohol Abuse and Alcoholism Clinical Investigations Group (NCIG) Study Group. 2019. Gabapentin enacarbil extended-release for alcohol use disorder: a randomized, double-blind, placebo- controlled, multisite trial assessing efficacy and safety. Alcohol Clin Exp Res, 43(1):158-169. PMID: 30403402.

Data Access Application Procedure and Access Policy

The NCIG 006 data set contains individual level data and is categorized as a controlled access data set. Access to the data will only be granted to approved researchers by the NIAAA Data Access Committee (DAC).

To receive access to the NCIG 006 data, the Applicant Principal Investigator must: (1) complete this Data Access Application form and (2) obtain a fully executed Data Use Agreement (DUA). The DUA is designed to define the allowable uses of the data set and to protect the confidentiality of the NCIG 006 participants. The DUA must be signed by an authorized institutional official that can legally bind the Applicant Principal Investigator's institution. This is ordinarily someone from the Applicant PI's technology transfer office. Completed applications may be submitted by email to:

Email: **niaaa-dac@mail.nih.gov**

(Application starts on the next page)

NCIG 006

Data Access Application

Title of Research Project:

Date of Application: _____

Applicant Principal Investigator (P.I.):

Name: _____

Affiliation: _____

Title _____

Address: _____

Telephone: _____

E-Mail: _____

Degree(s) Held: _____

Major Discipline/Field of Study: _____

May we contact you in the event that updates are made to the NCIG 006 data set and/or documentation? **Yes** ☐ **No** ☐

Authorized Institutional Official

Name: _____

Affiliation: _____

Title: _____

Address: _____

E-Mail: _____

FWA # _____

I have read the notes on access below and will contact the DAC with any questions **Yes** ☐

Notes on access to the NCIG 006 data:

- Only researchers who will be working on the **same Research Project under direct the supervision of the Applicant Principal Investigator (PI) at the Applicant PI's same institution** (including, but not limited to, graduate students, postdocs, data analysts, and investigators working under the Applicant PI for this project) **will be covered by this application and the DUA.**

- Researchers who will be working on the same Research Project in collaboration with the Applicant PI but are part of a **different institution** and will need direct access to the requested database are NOT covered by this application. These researchers must submit their own application and DUA to get access to the requested datasets.

- Researchers who are affiliated with the Applicant PI's institution but are working on a **separate research project** not described in this application should submit their own application and DUA.

- Individuals who may contribute to scientific papers and other works in collaboration with the Applicant PI, but do not have direct access to the requested datasets, do not need to submit an application or complete a DUA.

- If a student wishes to use this dataset in a thesis or dissertation, a faculty sponsor must submit this application and be listed as the Applicant PI.

Exhibit A

Research Project Description

Please briefly describe your research plan in the space below.

Exhibit A

Research Project Description
Continued - Extra Space