MYASTHENIA GRAVIS FOUNDATION OF AMERICA, INC.®

Open Label Study of Subcutaneous Immunoglobulin (SCIg) In Myasthenia Gravis

Study Purpose: Determine whether Hizentra is a safe and effective treatment for people with Myasthenia Gravis.

Recruitment Information:

Study Type: Interventional

Status: Recruiting

Target Patient: Myasthenia Gravis patients stable on IVIG over the age of 18.

Eligible Ages: 18 years and older

For more information visit:https://clinicaltrials.gov/ct2/show/study/NCT02100969?term=myasthenia+gravis&rank=25

Inclusion and Exclusion Criteria:

Inclusion Criteria: - Must have MGFA grades 2, 3, or 4 generalized MG, according to the MGFA classification system

- Elevated AChR or MuSK Ab
- Patient's signs and symptoms should not be better explained by another disease process
- IVIG maintenance dose of .2 to 2 gm/kg/4 weeks or equivalent dose administered every 2-4 weeks
- Stable IVIG for at least 3 cycles
- Able to complete the study and return for follow-up visits
- Able to give written informed consent before participating in the study

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Exclusion Criteria: - History of chronic degenerative, psychiatric, or neurologic disorder other than MG that can produce weakness or fatigue
- Other major chronic or debilitating illnesses within six months prior to study entry
- Female patients who are premenopausal and are (a) pregnant, (b) breastfeeding, or (c) not using an effective method of double barrier birth control
- Altered levels of consciousness, dementia, or abnormal mental status
- Thymectomy in the previous three months
- History of renal insufficiency or liver disease
- Skin disease that would interfere with assessment of injection site reaction
- History of severe reactions to IVIG or SCIg
- Participation in a research study within the last 3 months
- Treatment with rituximab or other biologics within 12 months of study entry
- Unable to provide informed consent

Study Information:

Sponsor: Mazen Dimachkie, MD

Principal Investigator: Mazen Dimachkie, MD

Study Coordinator: Kiley Sims

Type of Study: Phase 2 Interventional

Study Duration: 16 weeks

Single Center/Multi-center: Multi Center

Travel Funds Available: ☒ Y ☐ N

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Find A Center Near You:

List Sites Here

Site: University of Kansas Medical Center

PI: Mazen Dimachkie, MD

Coordinator: Kiley Sims ksims2@kumc.edu 913-945-9922

Site: Phoenix Neurological Associates

PI: Todd Levine, MD

Coordinator: Lynette McKinney lmckinney@pnal.net

Site: University of Texas Southwestern Medical Center

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