MGFA Study Web Content:

Study of Pyridostigmine with Ondansetron in Subjects with Anti-AchR Positive Myasthenia Gravis

Study Purpose: Treatment

Recruitment Information:

Study Type: Randomized

Status: Phase 2

Target Patient: 18 Years and older – MG patients

Eligible Ages: 18 Years and older

Link to appropriate websites http://dastherapeutics.com/

Inclusion and Exclusion Criteria:

Inclusion Criteria: diagnosed with myasthenia gravis and who are currently taking pyridostigmine and experienced pyridostigmine-related GI side effects within the past 7 days. GSRS rating of at least Moderate discomfort on questions 5, 11, and 12. Subjects must be willing and able to complete a GI symptom diary within a consistent timeframe on a daily basis. Subjects must be able to tolerate a pyridostigmine dose of 30mg TID. Must be clinically stable in judgement of treating neurologists for past 3 months. Must have AchR antibody positive MG. Subjects must be able to swallow liquids. Subjects must be in good health as determined by their medical history, physical examination, vital signs, and laboratory tests. A subject with a medical abnormality may be included only if the investigator or designee considers that the abnormality will not introduce significant additional risk to the subject's health or interfere with study objectives. Subjects must have signed an informed consent form indicating that they understand

the purpose of and procedures required for the study and are willing to participate in the study and comply with the study procedures and restrictions.

Exclusion Criteria: Any acute or chronic diseases which are associated with GI distress (such as nausea, vomiting, or diarrhea), which could interfere with the subjects' safety during the trial, expose them to undue risk, or interfere with the study objectives. History or presence of hepatic, or renal disease or other condition known to interfere with the absorption, distribution, metabolism, or excretion of drugs. History of substance abuse, known drug addiction, or positive test for drugs of abuse or alcohol. Patients currently using marijuana for any reason (medical or recreational). Known hypersensitivity to pyridostigmine, or to ondansetron or similar 5-HT3 serotonin receptor antagonists. ECG changes including QT interval prolongation and congenital long QT syndrome. Electrolyte abnormalities (e.g., hypokalemia or hypomagnesemia), congestive heart failure, bradyarrhythmia's or other medicinal products that lead to QT prolongation. Treatment with drugs affecting peripheral cholinergic transmission within 1 month of study entry (with the exception of pyridostigmine). Subjects unlikely to co-operate during the study, and/or be questionably compliant in the opinion of the investigator. Patients currently being treated with narcotics. Patients being treated with aminoglycoside antibiotics, which are contraindicated in myasthenia gravis. Patients unable to be contacted in case of an emergency. Intake of an investigational drug within 30 days of study entry. Pregnancy and women of childbearing potential not willing to follow the birth control requirements as described in the informed consent or breastfeeding. History or presence of obstructive pulmonary disease or urinary obstruction (contraindication for pyridostigmine). This use of selective serotonin reuptake inhibitors (SSRI's).

Study Information:

Sponsor: DAS-MG, Inc.

Principal Investigator: Henry Kaminiski

Study Coordinator: Radwa Aly

Type of Study: Randomized

Study Duration: April 30, 2022

Single Center/Multi-center: Single Center

Travel Funds Available: ☐ Y ☐ N

Find A Center Near You:

List Sites Here

Site: George Washington University, Washington DC, United States 20037

PI: Henry Kaminiski

Coordinator: Click here to enter text.
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