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CC-CHOC Pediatric Point Person Project (P4)

Protocol Information Form

Follow this link to indicate your interest in Protocol **#11 Migraine** https://redcap.ctsacentral.org/surveys/?s=7Gifps

Submitted May 21, 2012

Participant ID #11 Migraine

Sponsor CRO

Study Title A Multicenter, Double-blind, Randomized, Placebo-Controlled, 4-armed Parallel Group Study to Evaluate the Safety and Efficacy of Study Drug 0.5-, 2.5-, and 5 mg Nasal Spray in the Treatment of Acute Migraine Headache in Adolescents

Target Population male and females 12-17 yrs of age with an established diagnosis of migraine, as defined by IHS or IHS criteria

Study Objectives To evaluate the efficacy of study drug nasal spray 0.5, 2.5, and 5 mg with placebo in acute treatment of migraine headache in adolescents, as measured by the primary end point of pain free status at 2 hrs post treatment. Fulfillment of the FDA PREA commitment

Key Inclusion/Exclusion Criteria INCLUSION

-An established diagnosis of migraine (history indicating the presence of migraine for at least1 year) with or without aura as defined by the IHS or IHS-R criteria. Patients with medical history of migraine for at least 1 year prior to screening as defined by IHS or IHS-R criteria without a historic documentation of migraine may be considered for entry after the history has been established and discussed with the medical monitor.
-A minimum of 2 migraines, considered to be moderately/severely disabling, per month (by history);
-A medical history of usual untreated migraine duration of ≥4 hours for any -month period prior to screening (Visit 1);
-A history of migraine attacks occurring at intervals of >24 hours apart, which is confirmed during the run-in and placebo challenge period;
-A BMI of ≤97th percentile for age

EXCLUSION
-A history of basilar, ophthalmoplegic, or hemiplegic migraine headache or any potentially serious neurological condition that is associated with headache; agonist drug (in the opinion of the investigator);
-Had a diagnosis or suspicion of drug-induced or chronic daily headaches within 1 year;
-Has 14 or more non-migraine headache days each month for 3 months before the screening visit;
-Has uncontrolled hypertension defined as systolic or diastolic BP that exceeds the 95th percentile for age and height;

-Has used monoamine oxidase-A (MAO-A) inhibitor, methysergide, methylergonovine, or cimetidine in the 2 weeks before randomization or an SSRI 4 weeks before randomization; if the patient has been on stable dose of SSRI for 8

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weeks (2 months) prior to randomization, they may be included in the study.
-Has any recent history of abuse (in the previous year) of alcohol or other drugs including drugs for the acute treatment of headache;
-***Responds to the placebo challenge during the run-in period (ie, migraine headache intensity is mild or none at 2 hours after the placebo challenge).

Study Synopsis

- 30-day run-in period beginning at Visit 1
- Patients will be dispensed 1 dose of single-blind placebo and will treat 1 episode of migraine headache.
- Patients will not receive any double-blind, active study drug during the run-in period
- Patients will be permitted - with the exception of the placebo challenge - to treat their migraine(s) headache with their usual migraine treatment medications.

The following restrictions apply in this study during the placebo challenge and treatment period:

- Treat headache within 30 minutes of onset of moderate to severe headache pain reaching moderate or severe intensity.
- Be completely symptom-free from any previous headache.
- Initiate treatment of the migraine headache with only the study drug provided.
- Before taking the study drug, patients must not have:
  - Treated this headache with any other medication,
  - Received any ergotamine or ergotamine-like derivative (eg, dihydroergotamine, methysergide) or triptan (5HT1B/1D agonist) in the 24-hour period before treatment with the study drug,
  - Used opiates in the last 24 hours;
- After taking the study drug, patients must not:
  - Sleep or nap for 2 hours,
  - Use rescue medication within 2 hours of taking the study drug
  - Use an ergotamine or ergotamine-like derivative (eg, dihydroergotamine, methysergide) or non-study triptans (5HT1B/1D agonist) for 24 hours.

Patients will be allowed to continue any medication being taken at the time of entry into the study.

Total Number of Patients to be Enrolled 1000

Enrollment Period Ongoing. Last patient in Oct 2013

Miscellaneous Details/Requirements Duration: 14 weeks/3 Visits

Subjects are provided with paper diaries to record Migraine HAs for 30 days during placebo run-in. Sites should be able to enroll 7 randomized patients. The SF rate is @ 51% largely due to the placebo responders at the 2 hr time point post study drug administration during the 30 day run-in period

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Any question? Email ctsa_childhealth@ctsaC4.org