Plan Overview

A Data Management Plan created using DMPTool

Title: Data Management Plans for the United States Migraine Study Protocol

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Funder: National Institutes of Health (nih.gov)

Funding opportunity number: 123465

Template: NIH-GEN: Generic

Last modified: 09-28-2015

Data Management Plans for the United States Migraine Study Protocol

Project Information

This Data Management Plan (DMP) entails the data which will be collected from a study conducted on behalf of the United States Migraine Study Protocol Group. The study is being conducted to assess rizatriptan's effectiveness in treating acute migraine at its onset versus in a later phase of the attack.

The study will ask those who experience migranes to treat their headaches twice; once with rizatriptan at the early onset of a migraine, and again with rizatriptan once the migraine becomes more severe. The patients will then be asked to report how they felt after using the medication each time. The study will assess: time to onset of headache relief, headache severity 2 hours postdose and whether or not patients became largely symptoms-free (including associated symptoms), and when they were able to resume normal activities.

General Data Management Plan Information

This study is being conducted to draw conclusions about the impact timing has on the medical benefits of the medication. The results will be used to better inform rizatriptan users on when they should be taking their medication to achieve maximum migraine relief in the quickest time possible. The results will also be shared accross the United States Migraine Study Protocol Group. This Data Management Plan is intended for review by the USMAP Group before disemination of the results.

Policies for Access and Sharing

There are no requirements for making the results of the study private. All participants have signed waivers to be able to participate in the study, and to have their results shared, with the exception of any personal information. The USMAP group wishes to make their results available to the public, for anyone who is interested in taking rizatriptan or has questions about the drug, and for anyone within the USMAP group who was not directly part of the study.

Legal Guidelines and Requirements

The results of this study will not contain any personal information of the participants involved, nor will it contain any unique personal identifiers that could cause assumptions to be made about those invovled. In order to assure that the results can be shared publicly, precautions have been taken to ensure that the participant's identities are kept anonymous.

Types of Data Produced

The data being produced from this study will include statistical values written down and made into charts. There are a number of variables being observed (time drug was taken, headache severity 2 hours postdose, etc.), and each of the results will be calculated and formed into a visual aid. Along with the charts, a report will be written up including the statistics and the conclusions that can be drawn from the results of the study.

Plans for Archiving and Preservation

There are different plans for archiving and preserving the data for the short term and the long term. However, for both plans security is a concern. The results of the study will be made public, but there is always a concern that someone may attempt to steal the data and conclusions and claim the study for their own. To protect against this, we are going to store and archive the data on a secure, password protected system that conducts a back up daily.

Short Term

The short term plans for archiving and preserving the data includes saving the results on the USMAP Group website. The results of the study will be dated and saved so that future researchers have access to the information.

Long Term

The long term plans for archiving and preserving the information involve saving the results on the USMAP group database once the results of the study become outdated. Although the results may be old and possibly irrelevant, we still want furture USMAP group members to have access to the study that will be conducted, either to base their studies off of or to encourage further conclusions to be drawn.
