ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
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Study Identification

Unique Protocol ID: EPILEPSIA-MEXICO
Brief Title: National Registry of Epilepsy in Mexico
Official Title: National Registry of Epilepsy in Mexico
Secondary IDs:

Study Status

Record Verification: May 2020
Overall Status: Not yet recruiting
Study Start: May 2020 [Anticipated]
Primary Completion: May 2021 [Anticipated]
Study Completion: November 2021 [Anticipated]

Sponsor/Collaborators

Sponsor: Programa Prioritario de Epilepsia
Responsible Party: Sponsor
Collaborators: Medicaweb, S.A.C.V.

Oversight

U.S. FDA-regulated Drug: No
U.S. FDA-regulated Device: No
U.S. FDA IND/IDE: No
Human Subjects Review: Board Status: Approved
    Approval Number: 2019-07-11
Board Name: Francisco Rubio Donnadieu
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Data Monitoring: Yes
FDA Regulated Intervention: No

Study Description

Brief Summary: The National Registry of Epilepsy in Mexico aims to be an observational, multicenter, and nationwide study about Epilepsy in Mexico. This project is proposed as the first registry about the diagnosis and treatment of epilepsy in Mexico. The participation of major health institutions, both public and private, of each state to ensure that the registry is representative of the country is planned.

Detailed Description: Introduction Epilepsy is a brain chronic condition characterized by the recurrence of unprovoked motor and non-motor seizures. A seizure can be defined as the transient appearance of signs and/or symptoms due to excessive abnormal neuronal activity in the brain.

The International League against Epilepsy (ILAE) proposes that epilepsy should be considered a brain disease based on at least one of the following conditions: (1) at least two unprovoked (or reflex) seizures occurring more than 24 hours apart; (2) one unprovoked (or reflex) seizure and a probability of further seizures similar to the general recurrence risk (at least 60%) after two unprovoked seizures, occurring over the next ten years; (3) diagnosis of an epilepsy syndrome.

Epilepsy is one of the most common neurological diseases worldwide, affecting around 60 million people of all ages around the world. The risk of premature death in people with epilepsy is up to three times that of the general population. The lives of people with epilepsy are often impacted by stigma, discrimination, and human rights violations.

Nearly 80% of people with epilepsy live in low- and middle-income countries (LMIC), where treatment gaps exceed 75% in most low-income countries and 50% in most middle-income countries. Unfortunately, the lack of epidemiological registries about this disease makes early diagnosis and effective treatment difficult, thus increasing its prevalence.

Design and methods The National Registry of Epilepsy in Mexico aims to be an observational, multicenter, and nationwide study about Epilepsy in Mexico. This project is proposed as the first registry about the diagnosis and treatment of epilepsy in Mexico. The participation of major health institutions, both public and private, of each state to ensure that the registry is representative of the country is planned. It seeks for wide geographical distribution to compare the quality of care between the different geographical areas of the country.

Data will be registered in an electronic case report form (CRF) stored in a centralized database in which all the necessary data for the study will be included. The study variables will be (1) demographic, (2) from diagnosis and its clinical manifestations, (3) results of laboratory tests and cabinet examinations, (4) treatment, previous and current, (5) clinical variables of concomitant diseases and factors that trigger or precipitate seizures, (6) frequency and number of seizures, and (7) type of medical care. Data collection will be performed from the usual clinical practice through the participating researchers themselves, the patient's medical history at the time of inclusion in the study, and data from the patients through a mobile app during the follow-up period, developed following updated information from the Clinical Guidelines of the Epilepsy Priority Program published in 20194 which are adhered to the current concepts of ILAE.

Demographic and clinical data will be obtained (focal or generalized, motor or non-motor seizures) and the general medical condition of the patient will be evaluated as stated in the Clinical Guideline of the Epilepsy Priority Program4 from the usual clinical visits and during the 6-month follow-up. According to the incidence of epilepsy reported worldwide and considering the Mexican population treated in the participating hospitals, the inclusion of at least 15,000 patients is estimated.

Objectives To know the current status of the diagnosis and treatment of epilepsy in Mexico in order to identify the clinical characteristics, treatment trends, and evolution during the 6-month follow-up, as well as the adherence to current clinical practice guidelines.

Inclusion and exclusion criteria Candidates for the registry are those patients of any gender, older and any age who present an Epilepsy diagnosis according to the current definition of the ILAE 2014.

Sites The Epilepsy Comprehensive Care Centers (CAIE), members of the Epilepsy Priority Program (PPE) of the Healthcare Sector in Mexico will participate, all with knowledge and experience in the diagnosis and treatment of patients with epilepsy.

Data analysis Descriptive and differential statistics will be used according to the observation obtained. For continuous variables, mean, standard deviation (SD), standard error of the mean (SEM), 95% confidence interval (CI 95%) minimum, percentile 25 (P25), median or percentile 50 (P50), percentile 75 (P75) and maximum, number of patients (n) and number of lost data will be obtained as descriptive statistics. For categorical variables, % will be obtained from the total and number of patients (n) in each category. Lost data will be treated as a new category.

Differences between continuous variables with normal distribution will be examined by Student's t-test. The Wilcoxon Sum-Rank Test will be used when continuous variables have failed in normality tests. To analyze categorical variables, chi-square will be used by the Fisher exact test or Yates correction. A two-tailed test with a value of $p < 0.05$ will be considered statistically significant.

Conditions

Conditions: Epilepsy

Keywords:

Study Design

Study Type: Observational [Patient Registry]

Observational Study Model: Case-Crossover

Time Perspective: Prospective

Biospecimen Retention: None Retained

Biospecimen Description:

Enrollment: 15000 [Anticipated]

Number of Groups/Cohorts: 1

Target Follow-Up Duration: 6 Months

Groups and Interventions

Outcome Measures

Primary Outcome Measure:

1. Number of patients treated for epilepsy in 70 public hospitals in the health sector in Mexico, divided by age groups.

We have a database that will be used to capture patients separated by age, newborn, pediatric age and adults, analyzing how many belong to each age group with an individual accounting to know the total absolute number.

[Time Frame: Four months]

2. To know the type of epileptic crisis, the type of epilepsy and the type of epileptic syndrome presented by patients who are treated for this disease in 70 public hospitals in the health sector in Mexico.
We have a database that will be used to capture patients divided by type of epileptic crisis that they present, both focal onset, generalized onset, or unknown onset. By the type of epilepsy that they present either focal, generalized, mixed, both focal and generalized or unknown epilepsy. And those who present characteristics of an epileptic syndrome register them. In this way we will have absolute numbers for each category of these three items.

[Time Frame: Four months]

3. Number of patients with epilepsy, separated by etiologies treated in 70 public hospitals in the health sector in Mexico.
We have a database that will be used to capture patients separated by six specific etiologies, as currently recommended by the International League Against Epilepsy, structural, genetic, immune, infectious, metabolic or unknown, accounting for those who register each group to know the total absolute number.

[Time Frame: Four months]

4. To know the type of comorbidity presented by patients treated for Epilepsy in 70 public hospitals in the health sector in Mexico.
We have a database that will be used to capture the different comorbidities that patients present, some of them may have more than one comorbidity and it is interesting to quantify which are the most frequent of this group of patients treated in hospitals in the sector. public from Mexico regardless of the age of the patient, although later a more frequent sub-analysis can be made by age group and comorbidity.

[Time Frame: Four months]

5. To know the type of antiepileptic drugs that have been used and are currently used by patients treated for Epilepsy in 70 public hospitals in the health sector in Mexico.
We have a database that will be used to capture the drugs previously used by patients with epilepsy and what has been the reason for not taking them anymore, either due to lack of effectiveness or adverse effect, indicating by devices and systems in where it presented the adverse effect. In the same way, the antiepileptic drugs used by patients with epilepsy to control their disease will be known and accounted for.

[Time Frame: Four months]

6. Number of patients in spatial groups such as those in the newborn, pregnancy, with epilepsy surgery and with concomitant diseases treated by Epilepsy in 70 public hospitals in the health sector in Mexico.
We have a database that will be used to capture patients separated by age, newborn, pediatric age and adults, analyzing how many belong to each age group with an individual accounting to know the total absolute number.

[Time Frame: Four months]

Eligibility

Study Population: Candidates for the registry are those patients of any gender and any age who present an Epilepsy diagnosis according to the current definition of the ILAE 2014.

Sampling Method: Non-Probability Sample

Minimum Age:

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria

- Patients seen in an institution in the public sector of Mexico that belong to the Epilepsy Priority Program
- Informed consent and assent of participation in the project
- Patients with any form of epilepsy
- Patients seen by a Pediatric Neurologist or Neurologist

Exclusion criteria

- Patients who decide at any time not to participate
- Incomplete data of their disease
- Non-epileptic seizures
- Inadequate information from the patient, family member or informant

Contacts/Locations

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Study Officials:

Locations:

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information: