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Validation of medical device mjn-SERAS for early detection of epileptic seizures in refractory epilepsy patients in a normalised environment: A prospective, multicentre, pilot clinical study protocol

Seizure forecasting

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Background

Hypothesized that the use of an intra-aural EEG device (mjn-Seras) will allow the recording of EEG activity and the subsequent processing of the data by the AI algorithm to anticipate the event of suffering an epileptic seizure in those patients already diagnosed previously; and consequently, generate alerts prior to the onset of clinical symptomatology that allow the patient to take appropriate safety and prevention measures, and even alert of the possible future situation

Materials & Methods

A prospective, multicentre, pilot clinical trial is proposed to validate the mjn-SERAS medical device, already CE marked. This new validation will be in the participant's normalized environment, in individuals over 2 years of age, with a diagnosis of refractory epilepsy, which will make it possible to determine the impact of the mjn-SERAS device on the early detection of epileptic seizures. The sample size determined is an $n=150$. The sensitivity, specificity, PPV and F-Score of the device will be analysed. Also, the degree of satisfaction of patients and their caregivers, including the impact on quality of life.

Results & Conclusions

The expected results of the study is to reach the 75% sensitivity with epileptic seizures, F-Score, assimilated to specificity over 75%, and a Positive Prediction Value over 50%. The False Alarm Rate must be a maximum of 1 per day. Reduction of caregivers need is expected to be reduced a 20% and an improvement of quality of life by 20%.

This study proposes the use of the mjn-SERAS device during the day-to-day life of the patient, to analyse its performance in generating alerts prior of the clinical manifestation. In addition to the evaluation of these preventive alerts that we can associate with the physical sphere of the concept of health, we are going to determine, study and analyse the impact of the mjn-SERAS device on psychic and/or mental well-being as well as its repercussion on the social well-being of people with refractory epilepsy.

