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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

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Introduction

Introduction Epilepsy is a chronic disease with approximately one third of patients resistant to anti-seizure medication (ASM). Outpatient follow-up is subjective according to the patient's account and the treating physician's interpretation of the information received. However, there are currently no mobile devices that allow early detection of seizures, the evolution of the disease, the severity of seizures, their frequency or duration. Hypothesized that the use of an intra-aural EEG device (mjn-Seras) will allow the recording of electroencephalographic activity and the subsequent processing of the data by the artificial intelligence algorithm of MJN 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

Methods

A prospective, multicentre, pilot clinical trial is proposed to validate a medical device (mjn-SERAS device), which has already been validated and certified in Europe by

BSI Group (CE2797). 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 and the generation of a pre-seizure alert with a time window of a minimum of 1 and a maximum of 15 minutes. The sample size determined is an n=150 exposed individuals who meet the inclusion criteria. The sensitivity, specificity, positive predictive value, PPV and F-Score of the device will be analyzed. Also, the degree of satisfaction of patients and their caregivers, including the impact on quality of life and the degree of health perceived by the caregiver when alarms are generated to assess the possibility of a new epileptic seizure. Finally, to describe possible improvements in indicators of social relationships in different areas of personal development.

Results

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%.

Conclusions

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 in the case of the possibility of a high risk of epileptic seizures and to evaluate the concordance and prediction of the generation of early detection seizure alarms, prior to the identification of these clinically manifested events and collected by the patient or their relatives.

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.

