

Quality of life improvement and reduction of accidents, in day-to-day life results of the mjn-SERAS medical device for early seizure detection

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Background:

For patients with drug-resistant epilepsy, an alert system able to predict seizure onset through a medical device could significantly enhance their safety and independence, affecting the quality of life and the seizure-related accidents. Artificial Intelligence (AI) leverages forecasting models for early seizure detection. The objective of this study is to assess the impact of the mjn-SERAS in-ear EEG medical device, which uses AI-based seizure prediction.

Materials & Methods:

As part of the EIT Health Amplifier project, the SERAS-Home study recruited 77 already diagnosed epilepsy patients, recording 24,447 hours and 269 seizures. The study evaluates quality of life (QOLIE-31, EQ-5D-5L) and seizure-related accidents, comparing baseline assessments with a 6-month follow-up. The mjn-SERAS device is CE-marked, ensuring compliance with European Medical Device Regulations (MDR 2017/745). mjn-SERAS is a digital solution developed by MJN Neuroserveis and to be commercialised in Europe by Neuraxpharm as EPISERAS.

Results and Conclusions:

Total scoring of the QOLIE-31 has increased from initial average of 23,5 points to final average of 48,8 point, an improvement of 227%. Seizure-related accidents averaged before study was 26% of all seizures. At the end of study we reached a reduction, from 6% up to 11% of total seizures. The final accuracy of the individual models averaged 85%, with a sensitivity of 73%. The specificity was 98%. The False Alarm Rate (FAR) per day during interictal periods was 0,37.

We observed a clear improvement between the intervention group and the control group of patients, especially in seizure worry, emotional well-being, energy/fatigue and social function subscales, demonstrating that the use of the device contributes to a better quality of life for patients and a reduction of accidents, injuries, health costs and emergencies.

