

Cognitive profile in elderly epileptic patients treated with perampanel as first add-on

Institution

Epilepsy Center
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Objective

Primary endpoint:

- Effect of perampanel on cognition in elderly patients, measured by difference in EpiTrack scores at 6 and 12 months after add-on perampanel compared to baseline scores without perampanel

Secondary endpoints:

- Seizure reduction rate after Perampanel add-on (measured by seizure diaries and patients' reports)
- QOLIE-31 scores at baselines and at 6 and 12 months
- Adverse events and side effects after perampanel add-on (measured by seizure diaries, patients' reports and medical reports)

Methods

Inclusion criteria

- Epilepsy diagnosis
- Age ≥ 60 years, ≤ 87 years
- Antiepileptic monotherapy (first or second)
- Indication for Add-on epilepsy treatment with perampanel
- Benzodiazepines for other indications are allowed (insomnia, anxiety, etc.) as well as rescue therapy for seizures

Exclusion criteria

- Treatment with more than 1 AED in the past 3 months
- Epileptic status in the past month
- Contraindications for treatment with perampanel (As stated in the Summary of Product Characteristics (SmPC))
- Treatment with perampanel in the past year
- Diagnosis of neurodegenerative disorder with already known progressive cognitive decline
- Psychiatric comorbidity with history of alcohol/substance abuse
- Progressive encephalopathy including central nervous system tumors

Aim: minimum 50 patients

Patients will be screened in regular out-patient visits. Patients fulfilling inclusion criteria and willing to participate will be asked to sign the informed consent.

After signature of informed consent, the out-patient visit will be the Baseline visit. Patient's demographic characteristics and clinical data about the epilepsy will be noted as well as the number of previous AED therapies (differentiate between first or second monotherapy). Review of patients' diaries and reports to quantify seizure frequency. Neurological examination will be performed. Baseline EpiTrack and QOLIE-31 scores will be assessed directly at the baseline visit.

Follow-up visits will be planned at 6 and 12 months (as usually performed in a regular out-patient basis). Review of patients' diaries and reports to quantify seizure frequency since the last visit. Neurological examination will be performed. EpiTrack and QOLIE scores will be both at 6 and 12 assessed for comparison to the baseline.

In search for:

Partners to make a Swiss multicenter study

State of IRB approval:

Needed

Possible sponsoring by Eisai Pharma

Timeframe/Current status

Plan to begin in fall 2020 and recruit patients until June 2021

Contact

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