

Study Protocol

Study ID : 2019-A02748-49

Title : **Attentional Impairment in People With Epilepsy**

French abbreviation study : ETAPE

Study summary :

Epilepsy is one of the most common chronic neurological conditions. It leads to cognitive impairment in 20-50% of patients with a structural form.

In comparison with seizures, these cognitive disorders are a major additional factor in occupational, social and family disability. They are particularly frequent (50%) in temporal epilepsies and preferably concern memory and language skills.

The cognitive consequences of epilepsy are therefore well described in the following areas: episodic memory, language, executive functions.

Concerning attentional abilities, a recent review has highlighted the lack of work in this specific field in order to properly measure the prevalence and nature of attentional disorders in epileptic patients. Indeed, attentional abilities are often mentioned in studies, but attention is a complex domain defined by four modalities: alertness, selective attention, divided attention and sustained attention. No study systematically assesses all of these modalities.

The objective of this study is to evaluate the prevalence and nature of attentional disorders in epileptic patients compared to control subjects.

- **Primary outcome** : To evaluate the prevalence of attentional disorders in epileptic patients compared to control subjects.
- **Secondary outcome** : Assess the nature of attentional disorders in relation to executive functions and the level of anxiety-depression.
- **Main endpoint** : D2 task (selective attentional task)
- **Other measures** : attentionnal task (see below); executive task and depression and anxiety scale (total duration : around one hour and 10 minutes)

Attentional tasks description :

<p>Selective attention</p> <p>D2</p> <p>Test duration: 5 minutes</p>	
<p>Subtests</p> <p>Alertness</p> <p>TAP 2.2 – Alertness</p> <p>Test duration: 5 minutes</p>	<p>Examples</p> <p>Alertness</p> <p>Please note: The test will be conducted in two ways:</p> <p>First condition: A cross appears on the screen. Please press the key when the cross appears!</p> <p>Second condition: You will hear a signal and then the cross will appear. Please press the key only when the cross appears !</p> <p>Please press a key (cancel with X)</p>

<p>Divided attention</p> <p>TAP 2.2 – Divided attention</p> <p>Test duration: 6 minutes</p>	<p>Divided Attention / dual task</p> <p>You have two tasks in this test:</p> <p>First task: You will see a region on the screen in which a varying number of crosses appear simultaneously. When four of these crosses form a square, then please press the key as quickly as possible.</p> <p>Example:</p> <pre> x . x . x . x x . . x x . x . . </pre> <p>Second task: In this task you will hear a high and a low tone in sequence. You must decide whether the same tone occurs twice in a row. Please press the key as quickly as possible!</p> <p>Your task is to pay attention to both squares and tones at the same time.</p> <p>Please press a key (cancel with X)</p>
<p>Sustained attention</p> <p>TAP 2.2 – Sustained attention</p> <p>Test duration: 15 minutes</p>	<p>Sustained Attention</p> <p>In the following test, you will see patterns of different shapes, colours and sizes on the screen:</p>  <p>Your task is to press the key as quickly as possible whenever two successive patterns have the same shape.</p> <p>Please press a key (cancel with X)</p>

Executives task :

Digit span

Verbal fluencies

Inhibition task : subtest incompatibility in TAP battery

Flexibility task : subtest flexibility in TAP battery

Scales :

Neurological Disorders Depression Inventory for Epilepsy (NDDI-E)

Generalized Anxiety Disorder (GAD-7)

Population : Epileptic patients versus normal control

The inclusion criteria for patients are:

- Patients with epilepsy, according to the Fisher et al. (2005) criteria.
- Patient with written informed consent
- Affiliation to a social security insurance
- Individuals who have received full information about the organization of the research and have not objected to their participation and the use of their data.
- Person 18 years of age and older

The inclusion criteria for healthy subjects are:

- Individuals who have received full information about the organization of the research and have not objected to their participation and use of their data.
- Person 18 years of age and older
- Person with no neurological and/or psychiatric history

Duration of the inclusion period: 5 years

Duration of subject participation (2 visits): There may be a delay of up to 3 months between the inclusion visit with neurological screening and the planning of the neuropsychological assessment visit after which the subject exits the study.

Total research duration: 5 years and 3 months.

References

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Hudson, J. M., Flowers, K. A., & Walster, K. L. (2014). Attentional control in patients with temporal lobe epilepsy. *Journal of neuropsychology*, 8(1), 140-146.

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