First name:

Last name:

## Statistics, neuroscience: Exam 2022

Delphine Courvoisier, Denis Mongin, David and Tim

Data used for this exam are inspired from the Lancet Neurology article : Safety and efficacy of prophylactic levetiracetam for prevention of epileptic seizures in the acute phase of intracerebral haemorrhage (PEACH): a randomised, double-blind, placebo-controlled, phase 3 trial (https://www.thelancet.com/journals/laneur/article/PIIS1474-4422(22)00235-6/fulltext). Nevertheless, they are generated and are NOT the real data underlying the study, since these data were not provided by the authors.

PLEASE DO NOT READ THE ARTICLE DURING THE EXAM!

This is a randomized control trial, which aims at testing the efficacy of the drug levetiracetam in preventing epileptic seizure in patients with intracerebral haemorrhage. 50 patients were randomly assessed to two groups: 26 in a placebo group, and 24 in a levetiracetam group. The primary outcome was the number of patient having at least one electrographic seizure within 72h after inclusion. The secondary endpoint was the quality of life, assessed by the self-report questionnaire Stroke Impact Scale, at 6 months.

The hypothesis is that levetiracetam decrease the probability to have an epileptic seizure and increase the quality of life of the patients.

Description of the data:

* patientID: identifier of the patient
* group: group (placebo or levetiracetam) of the patient
* atleastoneseizure: 0/1 variable indicating if the patient had (1) or not (0) a seizure during the 72h hours after inclusion
* SIC: Stroke impact scale at 6 months

Each question requires an answer in a few sentences, and never more than half a page. PLEASE ANSWER ONLY THE QUESTION ASKED, WITHOUT WRITING ABOUT ANYTHING ELSE.

1. Describe each variable in a few sentences supported by graphs or numbers. Specifically, what can you say about the distribution of ICS? (15 points)
2. Present and interpret a descriptive answer (graph or summary measures, NO test or p-value) to the main hypothesis of the authors. (15 points)
3. Indicate which tests you use to test the hypothesis for the two outcomes, justify your answer (15 points)
4. Using the p-values obtained above, write two sentences, one presenting the formal definition of the p-value, and the other explaining, in non-technical but complete terms, what the results show. (15 points)

**Bonus:**

(5 points) Assuming a proportion of patients with at least one seizure of 35% in the placebo group and of 10% in the levetiracetam group, and considering an alpha threshold of 5%, a power of 80%, what should have been the sample size of ecah group for this randomized control trial?

(5 points) The authors used a multivariable analysis to adjust for center and a score for stroke. They found that the effect is even stronger for the seizure difference in the adjusted analyses. What is the name of this phenomenon? Please provide a short explanation in simple terms for lay people.