11/29/17

NCT01458990: Proton Pump Inhibitors and Dysbiosis in Cirrhosis

Safety analysis:

- A. <u>Adverse events:</u> related to PPI initiation (allergy, GI upset etc) or withdrawal (recurrence of symptoms, GI bleeding etc) will be analyzed using non-parametric tests.
- B. <u>Withdrawal from study</u>

Microbiota analysis:

Will be performed using multi-tagged sequencing of stool samples in pre vs post PPI (initiation) and before/after PPI withdrawal. Wilcoxon signed-rank matched pairs tests and Kruskal Wallis test will be used.