

Title: Pilot Study of Add-On Fycompa (perampanel) Treatment for Catamenial Epilepsy

NCT number: NCT05201703

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Statistical analysis plan:

The primary outcome (50% responder rate) will be analyzed using Chi square analysis. The secondary outcome, changes in seizure frequency from baseline to treatment, will be analyzed using paired t-test or ANCOVA. The pilot should provide data for calculation of the required sample size for demonstration of a significant difference or equivalence between the two groups with 80% power.