



Speak Freely: A Research Study for Adults Who Have Been Stuttering Since Childhood

November 18, 2022

Thank you for signing up for communications regarding the Speak Freely research study for adults who have been stuttering since childhood (<https://speakfreelyregistry.researchstudytrial.com/>). The study conclusions are given below.

This initial exploratory clinical research study was to learn whether ecopipam is safe in the population of adults with childhood onset fluency disorder (COFD) and whether ecopipam and the instruments to measure fluency changes are effective. This initial study was not intended to be evaluated by the FDA for prescription approval.

There were nine participating clinical research centers in the U.S. Approximately 13,000 people responded to social media information about the study and 120 people completed an in-clinic visit to determine their interest and eligibility.

Of these 120 people, 68 met the study eligibility criteria, with 35 participants randomized to ecopipam and 33 participants randomized to matching placebo. Safety was monitored by scheduled urine and blood draws, ECG, vital signs, physical exams, and questionnaires and surveys to assess mood and possible changes in movements. Effectiveness was monitored by the physician's judgement of improvement and questionnaires and surveys to measure disfluency.

Study conclusions:

From a safety perspective, adverse events were reported by 21 participants receiving ecopipam and by 9 participants who received placebo. The most frequent adverse events were somnolence (23.5%), fatigue (8.8%), insomnia (8.8%), and sedation (8.8%). None of the adverse events required hospitalization or medical care and all were listed as possible reactions in the informed consent agreement.

From an effectiveness perspective, there was a modest numerical improvement in all measures used to evaluate disfluency in people who received ecopipam, however, none of the results were statistically different from placebo at the end of the study.

Emalex is not planning to conduct further research studies to develop ecopipam as a possible treatment for COFD. **We thank the National Stuttering Association, the participants who volunteered, and the community for their support of this research study.**