Spyryx-101 Trial: A Phase 2 study on the use of SPX-101 inhalation solution in subjects with cystic fibrosis (Hope-1study SPX-101)

Phase: Phase 2
Treatment: SPX-101 or placebo
Age: 18 + years
Duration: 4 weeks

Study:
This study, examined the efficacy and safety on the use of SPX-101 which targets sodium channels in people with CF who were 18 years and older in the hope of increasing muco-ciliary clearance. Participants were randomized to receive either the study drug (SPX-101) at a 120 mg or a 60 mg dose or a placebo for a 4 week period. The primary end point to be measured was change in lung function as measured by the Forced Expiratory Volume in one second (FEV_1); measured between the groups taking the drug and the placebo (group not taking the drug).

Results:
91 participants were enrolled in the study. 83 participants completed the trial. The average change in FEV_1 in percent predicted for the group taking the 120 mg drug was 0.89; for the group taking the 60 mg drug dose the average change in FEV1 in percent predicted was 0.8; while the group taking a placebo medication had an average change in FEV_1 in percent predicted of 1.63. There were equal number of adverse events reported as percentage of participants in each group; 120 mg group = 70%; 60 mg group = 67%; placebo group = 68%. These were mostly increased cough, and sputum production across all groups with wheezing and bronchospasm reported in the groups taking the drug.

Conclusion:
In this study, the study drug (SPX-101) had a negative effect on the participants with CF. As a result no further study of this drug will be undertaken. The sponsor would like to thank all the people who participated in this study.

https://clinicaltrials.gov/ct2/show/results/NCT03229252