

First-in-class nasal spray demonstrates promise for migraine pain relief

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Researchers are developing a novel prochlorperazine nasal spray formulation as a potential new treatment for migraines. This work is being presented at the 2014 American Association of Pharmaceutical Scientists (AAPS) Annual Meeting and Exposition, the world's largest pharmaceutical sciences meeting, in San Diego, Nov. 2–6.

Migraines are manifested by severe pain and headache that can last anywhere from four to seventy-two hours, accompanied by nausea, vomiting, and sensitivity to both light and sound. Of the 100 million people that experience headaches in the United States, 37 million of them suffer from migraines. According to the Migraine Research Foundation, migraine ranks in the top 20 of the world's most disabling medical diseases, with someone in the United States going to the emergency room every 10 seconds for treatment.

Venkata Yellepeddi, Ph.D., along with his colleagues from Roseman University of Health Sciences, developed a preservative-free device-driven prochlorperazine nasal spray that could prove useful for compounding pharmacists specifically in the field of pain medicine. "Prochloperazine is a dopamine receptor antagonist that is widely used as an anti-nausea medication. Comparative clinical studies have shown that prochloperazine provides better pain relief than other anti-migraine drugs such as sumatriptan, metoclopramide, and ketorolac," said Yellepeddi. "Currently, there are no marketed nasal spray formulations of prochlorperazine available for the treatment of migraine. Prochlorperazine is only available in tablet form, which has delayed



onset of action." Yellepeddi and his team hypothesize that a nasal spray version of prochlorperazine will not only be effective, but fast acting and have better patient compliance overall. Furthermore, this novel product does not have any preservative-related adverse side effects, such as mucosal irritation which are normally seen with vehicles with preservatives such as benzalkonium chloride and potassium sorbate.

Yellepeddi used high performance liquid chromatography and microbiological assays to assess the stability of prochloperazine nasal spray. These studies demonstrated that the nasal spray was able to remain stable for up to 120 days with minimal degradation, therefore making it an effective treatment option for migraine patients.

The next stage of Yellepeddi's research is to test the safety, efficacy, and pharmacokinetic studies of the prochlorperazine <u>nasal spray</u> in rat animal models.

Provided by American Association of Pharmaceutical Scientists

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