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Evaluate the Efficacy , Safety and Tolerability of Zavegepant Nasal Spray For The Acute Treatment Of Migraine

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ABSTRACT

Zavegepant is a calcitonin gene related peptide inhibitor which is a new class of drug for acute attack of migraine. It is present in the form of nasal spray for treatment of acute attack of migraine. The objective of study is to evaluate the efficacy, safety and tolerability of this drug for acute attack of migraine. The study was a randomized double blind control trial in which adults (>18 years) with migraine were included in the study. Patients were divided with the help of a web based interactive response system and treated a moderate intensity migraine attack with zavegepant nasal spray 10 mg or placebo. Efficacy was evaluated by relief of symptoms 2 hour after use of nasal spray. 110 patients were randomly divided into 2 groups – group A (57 patients) and group b (53 patients). Group A was treated with 10 mg zavegepant nasal spray and group B was given placebo. Group A patients showed the significant relief in symptoms with some showing minor adverse effects such as nausea and crusting in nose. In conclusion zavegepant nasal spray 10 mg is effective for the acute treatment of migraine with good safety profile and tolerability.

Keywords: Zavegepant, Migraine.

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INTRODUCTION

For acute treatment of migraine various kinds of oral, parenteral and nasal spray are available. Most commonly used oral medications for acute treatment of migraine are 5HT 1b/1d receptor agonist such as sumatriptan, zolmitriptan and ergot alkaloids [1]. But because these oral drugs are slow acting, have poor bioavailability and tolerability patients have started to prefer intranasal spray due to their rapid action and good bioavailability. Intranasal spray are preferred over injectable drugs because they are easy to use. Intranasal triptans are ineffective in almost one half of the patients who used them and also they can not be given in patients who have cardiovascular disease therefore restricting there use in those patients. Intransal Dihydroergotamine is also very less effective in management of acute migraine attack and also they can not be given in various conditions such as hypertension, ischemic heart disease, coronary artery disease etc. however gepants are new class of antimigraine drugs which are effective intranasally for acute treatment of migraine. They have various advantages such as they can be given in cardiac disease patients such as hypertension, ischaemic heart disease, and coronary heart disease and in patients who are unable to tolerate oral medication due to gastrointestinal issues. New guidelines for the acute treatment of migraine recommends use of injectable and intransal spray for patients who do not respond to oral agents, patients with severe nausea and vomiting that interferes with administration or absorption of oral acute treatments and for those whom oral therapies are intolerable due to drug induced nausea or dysphagia. Zavegepant is a third generation calcitonin gene related peptide receptor antagonist (cgrp)[2]. Zavegepant nasal spray can be in dose ranging from 5mg to 40 mg and produces significant symptomatic relief of acute attack of migraine. studies have shown that has low drug to drug interactions and has good safety profile[3].

MATERIALS AND METHOD

The study was double blind randomized control clinical trial [4]. The study was conducted in various government and private hospitals. A total of 110 patients were included in the study. There were divided equally into the two groups – group A and group B. during the study six patients from group A and four patients from group B drops out from the study in between due to some unknown reason. the remaining patients in group A where given intranasal zavegepant spray for acute treatment of migraine and the other group B was given intra nasally a placebo formulation for acute treatment of migraine. Randomization was managed by an interactive web based response system. At the time of enrollment informed consent was taken. to record patients symptoms and response to treatment patients were provided with a electronic device patients were given a nasal spray which is containing either zavegepant nasal spray or placebo. They were instructed to use the nasal spray only if they start having

symptoms of acute migraine. Man and women of age more than 18 years were chosen who have mild to moderate symptoms of acute migraine lasting from 4 to 48 hours if left untreated with at least one year history of migraine [5]. Primary efficacy endpoints were relief from symptoms such as photophobia , phonophobia , aura etc . and secondary endpoints efficacy includes relief from headache after two hours of treatment.

RESULTS AND DISCUSSION

A total of 110 patients were taken for the study out of which 10 patients in group A and 5 patients in placebo group dropped out in the middle of the study due to some unknown reason. Group A was given zavegepant nasal spray for the acute treatment of migraine. Out of 47 patients in group A 32 patients showed the relief in primary efficacy endpoint symptoms such as nausea, vomiting, aura etc and 37 patients were reliefed from secondary efficacy endpoints symptoms such as headache post two hours of drug use. On the contrary in the group B which were given placebo nasal spray for treatment of acute migraine out of 48 patients only 21 patients got reliefed from primary efficacy endpoints symptoms and 30 patients were reliefed from secondary efficacy endpoint symptoms such as severe headache post two hour treatment of nasal spray. See table 1 to compare the relief of various symptoms in group A and group B.

Table 1: Comparison the relief of various symptoms in group A and group B

	Group A	**Group B**
Photophobia relief	35	22
Phonophobia relief	33	20
Nausea , vomiting relief	30	24
Headache relief at 60 min	34	21
headache relief after 2 hours	37	30
Rescue medication use within 2 hours	10	14
Return to normal function after 60 mins	34	20
Return to normal function after 2 hours	37	22

In group A four patients got mild symptoms such as nausea, vomiting, nasal dryness and crusting and no patients show any major adverse effects and in group B no adverse effects were seen. This randomized control clinical trial was performed to evaluate the efficacy and safety of zavegepant nasal spray for the acute treatment of migraine. The zavegepant 10 mg nasal spray were more effective than placebo for freedom from pain at 2 hour post dose and freedom from bothersome symptoms at two hours post dose. These results suggest that zavegepant may have a therapeutic role in the acute treatment of migraine as an alternative to oral and parenteral agents [6]. Patients are most likely to benefit from the use of zavegepant will be adults seeking a rapid onset of action. The nasal spray formulation may be a particularly advantageous non oral, needle free, approach to avoid exacerbation of nausea or vomiting, facilitate drug administration, and eliminate the effects of gastroparesis on drug

absorption. In the treatment of migraine, nausea and vomiting are reported to delay the use of oral medication and may be associated with slowed absorption. There is evidence that oral triptans cause treatment nausea and that a nasal form of sumatriptans caused less nausea than sumatriptans tablets in a head to head study. A nasal spray leads to a greater willingness to treat early and reduced risk of treatment nausea and vomiting. Zavegepant nasal spray has a short half life and rapid rate of absorption due which it has rapid onset of action. Zavegepant has long duration of action as indicated by sustained relief from pain and symptoms [7]. Zavegepant nasal spray was well tolerated and has a good safety profile .the adverse effects of nasal discomfort, nasal dryness, nasal congestion, nausea, vomiting were mild and resolved spontaneously without Intervention. But further studies and use by patients is required by the patients to evaluate the proper efficacy and tolerability of Drug.

CONCLUSION

Zavegepant 10 mg nasal spray is effective for the treatment of acute migraine with a good safety profile and tolerability and a rapid onset of action. The patients showed only minor adverse effects which resolved on their own with no treatment and does not showed any major adverse effects [8].

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