

THE BEST TREATMENT FOR CHRONIC MIGRAINE IS ONABOTULINUMTOXINA (BOTOX)

NO

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Chronic migraine is a progressive headache disorder that affects 1 to 2 % of the general population. It is a complication of migraine and it is characterized by headache frequency of at least 15 days per month. Chronic migraine is a severe disease and produces a significant disability in the sufferers. Few preventive medications have been studied for chronic migraine.

OnabotulinumtoxinA has been studied in the treatment of episodic migraine and chronic tension type headache with negative results:

In chronic migraine, after several trials with negative results, onabotulinumtoxinA was approved by the European and USA authorities for the treatment of chronic migraine after the publication of the PREEMPT I and II studies. (Two double-blind, randomized, placebo-controlled clinical trials for the treatment of chronic migraine with onabotulinumtoxinA, the Phase III REArch Evaluating Migraine Prophylaxis Therapy). After, a pooled data from the two trials and several subanalysis have been published.

There are several questions about the PREEMPT studies. The first is related with the inclusion criteria; in the PREEMPT 1 and 2 around 2/3 of the patients included had overused acute headache pain medication at baseline. If we follow the criteria of the ICDH II for chronic migraine these patients can't be classified as chronic migraine and should be categorized as medication overuse headache.

Another important point to rise is the fact of two different primary endpoints in both PREEMPT 1 (mean change from baseline in frequency of headache episodes) and PREEMPT 2 (mean change from baseline in frequency of headache days). Subsequent to study initiation, but prior to study completion and treatment unmasking, the protocol and statistical analysis plan for PREEMPT 2 was amended to change the primary and secondary endpoints, making frequency of headache days the PREEMPT 2 primary endpoint. Besides these methodological problems, the magnitude of the reported positive findings from the PREEMPT program was modest.

There are some small studies that compare OnabotulinumtoxinA with other drugs that have showed positive results in patients with chronic migraine (divalproex sodium and specially topiramate); in these studies the efficacy of OnabotulinumtoxinA haven't been superior to topiramate