Galcanezumab as a treatment for the prevention of Migraines

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INTRODUCTION

•12 % of the population suffers from migraines
•Along with cranial pain, patients can have visual disturbances, nausea, vomiting, dizziness, photophobia, osmophobia, and phonophobia
•Etiology poorly understood, but thought to involve release of substance P, calcitonin gene-related peptide (CGRP) and neurokinin A
•Diagnosis of migraine made clinically via history and physical exam
•Current treatment is characterized as preventative or acute
•Galcanezumab (a fully humanized monoclonal antibody approved in 2018) binds to CGRP and blocks its binding to its receptor

Clinical Question

•In adults aged 18-65 with chronic migraines, does subcutaneous galcanezumab as compared to placebo reduce the number of monthly migraine headache days reported by the patient?

METHODS

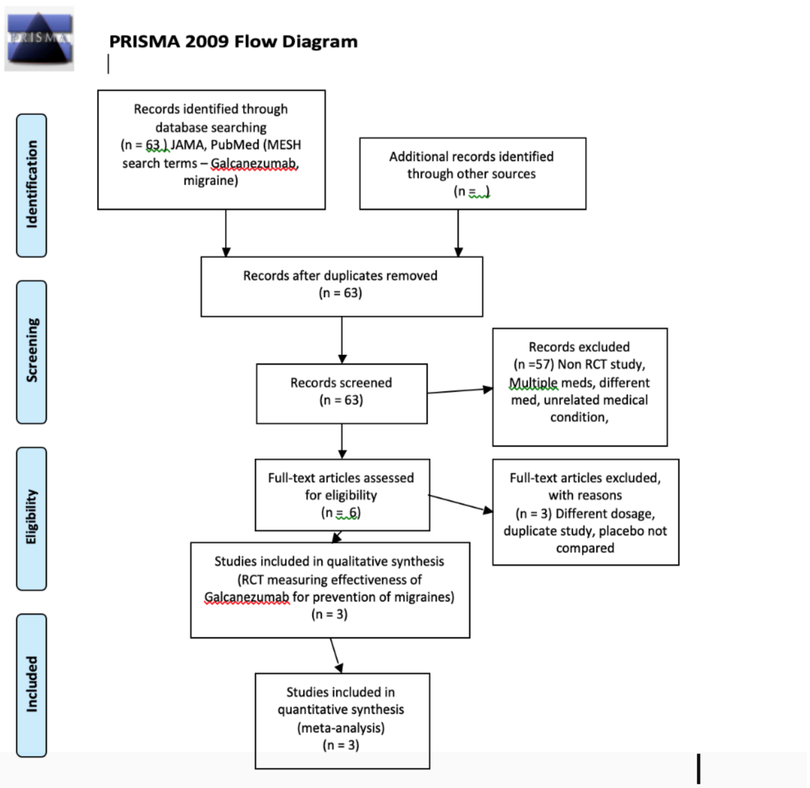

Figure 2: Prisma Diagram

RESULTS

	Study 1 Stauffer, et al.	Study 2 Rosen, et al.	Study 3 Detke, et al.
Objective	To demonstrate that galcanezumab is superior to placebo in the prvention of episodic migraine with or without aura.	To characterize adult patients with episodic migraine who achieved 100% response to galcanezumab treatment from two other studies.	To determin if subcutaneous injection of 120 mg and 140 mg galcanezumab is more effective in preventing total number of monthly migraine headache days (MHDs) in patients with a previous diagnosis of chronic migraines, as compared to placebo.
Study Type	Double Blind RCT	Post Hoc Analysis	Double Blind RCT
Sample Size	N=858 (120mg-213, 240mg -212, placebo-433)	N=1739 (120mg-436, 240mg-428, placebo- 875)	N=1113 (120mg – 278, 240mg-277, placebo-558)
Study Treatments	Galcanezumab (120mg and 240mg)	Galcanezumab (120mg and 240 mg)	Galcanezumab (120mg and 240 mg)
Follow Up Period	6 months	6 months	3 months
Conclusion	Galcanezumab 120mg and 240mg both achieved a statistically significant overall mean reduction in the number of monthly MHDs during treatment (4.7 and 4.6 days, respectively) when compared with placebo (2.8 days)	Treatment with galcanezumab 120 mg or 240 mg showed a greater effectiveness in achieving 100% response in reduction of MHD from baseline compared with placebo in the 6 month double blind phase.	Both Galcanezumab 120 mg and 240 mg doses demonstrated statistically significant superior effectiveness compared to placebo in the overall mean reduction in number of monthyly MHDs from baseline (*p* value <0.001).

Table 1: Summary of results

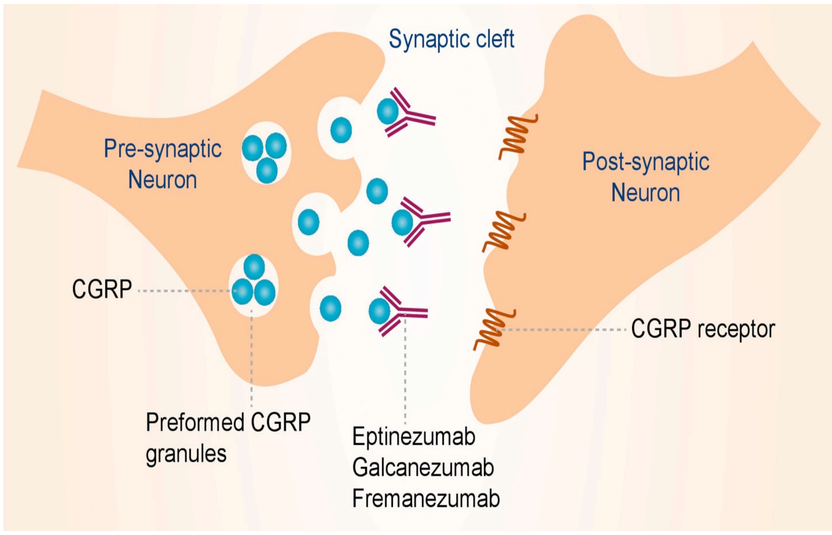

Figure 3: Action of Galcanezumab on CGRP

CONCLUSION

•Systematic review shows that galcanezumab is an effective medication that demonstrated a clinically meaningful and positive change
•Statistical benefit was demonstrated in all studies as compared to placebo
•There was no difference in efficacy between the 120mg and 240mg doses
•The most common adverse effect was found to be injection-site pain
•Since this is a realtively newly approved drug, further studies need to be conducted specifically on long-term adverse effects

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