



# American Academy of Neurology

## 58<sup>th</sup> Annual Meeting

April 6, 2006, San Diego, California

### Gelstat Is Effective in Relieving Migraine Pain in a Double-Blind, Placebo-Controlled Study

**Sheena K. Aurora, Alexis R. Vermaas, Patricia M. Barrodale, Seattle, WA** <sup>1</sup>

**OBJECTIVE:** To evaluate the efficacy of Gelstat™ Migraine (ginger extract and feverfew extract) in alleviating migraine in a prospective, randomized, double-blind, placebo controlled single attack study.

**BACKGROUND:** Migraineurs use over the counter (OTC) therapy often to relieve migraine attack despite the presence of effective prescription medications.<sup>2</sup> The reasons for this are manifold including accessibility, restrictions by insurance companies, dissatisfaction and concerns for side-effects. It becomes imperative therefore to evaluate OTC therapy of migraine with double-blind placebo controlled study.

**DESIGN/METHODS:** The study was approved by Western IRB. Fifty four patients were consented and forty completed the study. Randomization ratio for Gelstat vs. Placebo 2:1. Twenty-six patients treated with Gelstat and 14 patients with placebo. Patients were age matched mean 42.5 years on Gelstat and 43 years on placebo. Patients recorded symptoms in a headache diary at baseline, .5, 1, 2, 4 and 24 hours. Primary endpoint was pain freedom at 2 hours and secondary endpoints were relief from pain, nausea, photophobia and phonophobia.

**RESULTS:** Patients had an average of 4.6 headaches per month in both groups. 83% of patients were currently on triptans and 61% of patients on at least 1 prophylactic agent. 34.6% of patients had aura in the Gelstat group compared to 35.7% in the placebo group. Duration of migraines was 24.7 years in the Gelstat group compared to 24.3 years in the placebo group. Patients treating with Gelstat had significantly more pain relief at 2 hours 65% compared to placebo 36% ( $p=0.038$ ). Pain freedom at 2 hours was 19% for Gelstat compared to 7% for placebo (without statistical significance).

**CONCLUSIONS/RELEVANCE:** Gelstat is a reasonable option for pain relief for patients who want to treat migraines with OTC medications.

---

1. Presented at the American Academy of Neurology Annual Meeting, April 6, 2006. Dr. Aurora is co-director of the Swedish Headache Center in Seattle, a specialty headache clinic that treats more than 3,000 patients every year. She is board-certified in neurology and electrodiagnostic medicine, and has additional qualifications in clinical neurophysiology. Dr. Aurora was previously medical director of the Headache Clinic at Henry Ford Hospital in Detroit. Dr. Aurora has been widely published and lectures frequently on the topics of headache, migraine, and clinical neurophysiology. An experienced researcher, Dr. Aurora was one of the principal investigators of the first migraine program project funded by the National Institutes of Health.

2. Lipton RB, Hamelsky SW, Dayno JM. What do patients with migraine want from acute migraine treatment? *Headache*. 2002;42:3-9.