

**Grossmann W, Schmidramsl H. An Extract of *Petasites hybridus* is Effective in the Prophylaxis of Migraine. *Altern Med Rev* 2001;6(3): 303-310.**

Design: Randomized clinical trial

Population/sample size/setting:

- 60 patients (32 women, 28 men, mean age 29) treated for migraine at a neurology department in a municipal hospital in Munich, Germany
- The International Headache Society definition of 1988 was used to diagnose migraine headache
- Eligible patients had a minimum of 3 attacks per month in the 3 months before starting the study
  - o A run-in phase of observation, lasting 4 weeks, was required before treatment began; in this period, at least 2 attacks were required

Main outcome measures:

- Randomization to *Petasites* extract at a dose of two 25 mg capsules twice daily (total of 100 mg, n=33) or placebo capsules in the same manner (n=27)
- Treatment and observation lasted for 12 weeks, with patients seen at 4 week intervals
- Primary outcome was the frequency of migraine attacks per 4 weeks, although migraine days, duration, and intensity of attacks were also recorded
- At baseline, the group receiving *Petasites* had a mean of 3.3 attacks per month; after 12 weeks, this was reduced to a mean of 1.7 attacks per month
- For placebo, the frequency of attacks was reduced from a mean of 2.9 to a mean of 2.6 at 12 weeks
- *Petasites* was judged statistically superior to placebo for the main outcome
- There was a small increase in the frequency of migraine attacks in the *Petasites* group between 8 weeks (mean =1.3) and 12 weeks (mean=1.7); this was considered noteworthy and difficult to interpret, since there was also a rise in pain intensity and duration during the same time interval
- Adverse effects were not reported; both *Petasites* and placebo were well-tolerated; liver enzymes and blood pressure were not affected by treatment

Authors' conclusions:

- Extract of *Petasites hybridus* is well-tolerated and effective for prophylaxis of migraine
- The increase in headache duration and intensity observed between 8 weeks and 12 weeks may have been due to the small number of patients, but should be re-evaluated in a larger randomized clinical trial

Comments:

- The study is described as randomized and double blind, but the methods of randomization and blinding are unclear
- The increase in headache frequency between the second-to-last and the last observation periods also occurred in the later trial (Lipton et al, 2004)

- Some of the patients had previous treatment for migraine, but the details are not clear, and, since the recruitment details are lacking, there may have been few patients who had received numerous previous treatments without success

Assessment: Adequate for evidence that *Petasites* extract may reduce migraine frequency in patients with episodic migraine