

Hawthorn, California Poppy, and Magnesium Combination Found Safe and Possibly Effective for Mild to Moderate Anxiety

Reviewed: Hanus M, Lafon J, Mathieu M. Double-blind, randomized, placebo-controlled study to evaluate the efficacy and safety of a fixed combination containing two plant extracts (*Crataegus oxyacantha* and *Eschscholzia californica*) and magnesium in mild-to-moderate anxiety disorders. *Curr Med Res Opin.* January 2004;20(1):63-71.

Anxiety disorders are a common complaint among patients of general practice physicians. Pharmaceuticals used to treat anxiety disorders produce significant side effects. Anxiolytic phytotherapy may be used as an alternative to pharmaceuticals for the treatment of mild to moderate anxiety. In France, preparations containing

There were no significant differences between the drug and placebo groups before treatment. Both treatments produced a rapid and progressive fall in anxiety. However, the placebo effect was consistently smaller than that of the study preparation. There was a significant improvement in the total anxiety score ($P = 0.005$), somatic score ($P = 0.054$), and self-assessment ($P = 0.005$) in patients taking Sympathyl for 3 months. While the difference between treatment groups appeared to increase over time, a longer study would be needed to confirm this finding. The percentage of responsive patients (at least 50% fall in score) was significantly higher in the study drug group than the placebo group, by all assessment criteria. Typically studies that assess anxiolytics have a strong placebo response in the short run, so the findings were not surprising. The incidences of nausea and morning sluggishness were higher in the patients taking Sympathyl. (Four cases of nausea and three cases of morning sluggishness were reported in the Sympathyl group, but no such cases were reported in the placebo group.)



Hawthorn *Crataegus laevigata* Photo © 2005 stevenfoster.com.

hawthorn (*Crataegus laevigata* [Poir.] DC., syn. *C. oxyacantha* auct., Rosaceae), California poppy (*Eschscholzia californica* Cham., Papaveraceae), and magnesium are prescribed to treat anxiety disorders. Both of these botanicals are reported to have anxiolytic properties. Magnesium deficiency is thought to cause psychological disturbances. To the knowledge of the authors, there are no clinical studies confirming anxiolytic effects for hawthorn and California poppy. This paper reports on the efficacy of these botanicals for the treatment of anxiety disorders.

This multicenter, double-blind, randomized, placebo-controlled study was carried out in general practice offices in Paris, France, and the Paris area. Men and women ($n = 264$) with mild to moderate generalized anxiety disorder as diagnosed according to the DSM-III-R criteria participated. Patients received either 2 tablets of placebo or Sympathyl® (Laboratoire Innotech International, Arcueil, France) twice daily for 3 months. Sympathyl contains 75 mg of dry hydro-alcoholic extract of the flowering head of hawthorn, 20 mg of dry aqueous extract of California poppy herb, and 75 mg of elemental magnesium. Efficacy was assessed using the Hamilton anxiety scale, patient self-assessment, and the physician's clinical global impression. All of these are standard tests used to assess novel anxiety drugs. The safety of the preparation was also evaluated.



California poppy *Eschscholzia californica* Photo © 2005 stevenfoster.com

The authors conclude that the preparation is an effective and safe alternative treatment for mild to moderate anxiety. It would have been constructive if the trial design had also included an additional group of patients for comparison who were treated with benzodiazepines (the standard pharmaceutical treatment) to act as a positive control. The authors claim that they were not looking for a substitute for benzodiazepines but rather for an option with fewer side effects. Since Sympathyl was not directly compared to a benzodiazepine, the degree of efficacy for Sympathyl is not known (i.e., in relation to standard treatment with benzodiazepines). If its efficacy is as mild as its adverse effects, it may not be worth using. An additional study might provide clarification. 🌱

—Heather S. Oliff, PhD

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