Is St John’s Wort extract (LI 160) effective and safe for somatoform disorders?

METHODS

**Design:** Randomised controlled trial.

**Allocation:** Concealed.

**Blinding:** Double blind.

**Follow up period:** Six weeks.

**Setting:** Primary care settings, Germany; August 1999 to February 2000.

**Patients:** 184 people aged 18-65 years with somatisation disorder, undifferentiated somatoform disorder, and somatoform autonomic dysfunction (somatic subscore of the Hamilton Anxiety Scale (HAMA-SOM) >12 and the psychic subscore (HAMA-PSY) of 5 points below HAMA-SOM). For inclusion, participants required a Somatoform Disorders Screening Instrument (SOM) SOMS-2 (number of 53 conditions present in past three years) score of >4 (men) or >6 (women), and a SOMS-7 score (intensity of complaints in previous 7 days) of 12-30. Main exclusion criteria: major depression (Hamilton Depression Scale (HAMA) >12), substance abuse, other mental disorders including schizophrenia, unstable acute medical conditions, and suicide risk. People showing a decrease in SOMS-7 scores (>6 points) during a one week placebo run-in phase were also excluded from the trial.

**Intervention:** 300 mg St John’s Wort extract LI 160 taken twice a day for 6 weeks, or placebo.

**Outcomes:** Efficacy was measured with diagnosis scales (SOMS-7, HAMA-SOM) and the somatisation subscore of the Symptom Check List 90 Revised Scale (SCL-90-R), the improvement and efficacy subscores of the Clinical Global Impression (CGI), and the global judgement of efficacy by the patient. Ratings were assessed at weeks 0, 2, 4, and 6.

**Patient follow up:** Six weeks; 164/184 (89%) completed follow up.

MAIN RESULTS

At 6 weeks, St John’s Wort extract significantly reduced somatoform symptoms compared with placebo (45% vs 21%, p<0.0006).

CONCLUSIONS

300 mg of St John’s Wort extract LI 160 significantly improves somatoform disorder symptoms.

**Commentary**

In a traditional folk medicine and increasingly in more conventional practice, St John’s Wort has been used for many different conditions including depression, anxiety, psychosomatic disturbances, myalgia, bronchitis, asthma, gall bladder disease and other gastrointestinal complaints, nocturnal enuresis, gout, and rheumatism.\(^1\) This purported spectrum of efficacy makes St John’s Wort an ideal candidate for treatment of somatoform disorders. However evidence is scarce. Recent trends in trials for depression suggest that its effectiveness may be lower than previously assumed.\(^2\)

The study by Müller\(\text{et al}\) is important, as it expands the available evidence for St John’s Wort and somatoform disorder. Unfortunately, similar to the early depression trials, there are some methodological problems which may limit the clinical validity of the findings. For instance, placebo responders were to be excluded after the placebo run-in phase, leading to a bias in favor of St John’s Wort even if patients were subsequently randomized. Nine patients dropped out at this stage, although it is not clear whether they were placebo responders. However three of the four reasons given, including withdrawal of consent, poor compliance, and adverse events, may create a similar bias. Also the trial was conducted over a six week period, a short time span considering the chronicity of somatoform disorders. Finally the study reports extremely low rates of adverse events. The authors concede that they did not specifically investigate this, but they do not consider the possibility that patients experiencing side effects might not attribute those to St John’s Wort if they assumed that it was “natural” and hence safe. The significant potential of drug interactions by virtue of CYP 3A4 and p-glycoprotein induction is not discussed.\(^3,4\) However, this may be of importance in people with somatoform disorders also taking a variety of medications for their physical complaints.

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