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 (SOMS-SOM-2) (number of 53 conditions present in past three years) score of >4 (men) or >6 (women), and a SOMS-SOM-7 score (intensity of complaints in previous 7 days) of 12–50. Main exclusion criteria: major depression (Hamilton Depression Scale (HAMA) > 21 points) and somatoform disorder 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.

**MAIN RESULTS**

At 6 weeks, St John’s Wort extract significantly reduced somatoform symptoms compared with placebo. More people taking St John’s Wort were classed as responders compared with placebo.

**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. 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.

The study by Müller 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 favour of St John’s Wort even if patients were subsequently randomised. 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 these 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. However, this may be of importance in people with somatoform disorders also taking a variety of medications for their physical complaints.

Dr Ursula Werneke, MD, MSc, MRCPsych
Consultant Psychiatrist, Homerton University Hospital and Honorary Senior Lecturer, Institute of Psychiatry, King’s College, London, UK