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) score of >5 of 53 conditions present in past three years score of >4 (men) or >6 (women), and a SOMS-7 score of intensity of complaints in previous 7 days 12–30. Main exclusion criteria: major depression (Hamilton Depression Scale of >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 somatization 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 (see http://www.ebmentalhealth.com/supplemental_for_table). More people taking St John’s Wort were classed as responders compared with placebo (45% v 21%, p<0.0006).

CONCLUSIONS

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