

A prospective, open, uncontrolled study of a standardised extract of St John's wort (*Hypericum perforatum* L.; LI-160) as an aid in smoking cessation: preliminary results

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Objective

Although there are effective pharmacological aids for smoking cessation, such as bupropion and nicotine replacement therapy (NRT), there may be a role for non-nicotine, non-prescription pharmacological aids in smoking cessation. Nicotine may act as an antidepressant in some smokers, and the development of depression or a low mood after smoking cessation may lead to relapse. The aim of this study is to explore the effects of the herbal antidepressant St John's wort, together with individual behavioural support and counselling, as an aid in smoking cessation in order to develop a hypothesis for a randomised controlled trial (RCT).

Materials and Methods

This is an open, uncontrolled study of a standardised extract of St John's wort (LI-160; Lichtwer Pharma AG) with pharmacist-provided individual behavioural support and counselling for smokers who wish to quit. Smokers were recruited via advertisements and coverage in the UK local and national press. Volunteers who met inclusion and exclusion criteria attended an appointment with a pharmacist at a pharmacy in North London with private facilities. Inclusion criteria included: age 18 to 65 years; motivation to quit smoking, smokers of at least 10 cigarettes daily for 1 year. Exclusion criteria included: regular use of prescription medicines; use of nicotine replacement therapy or St John's wort within previous 6 months; pregnancy and lactation. Written informed consent was obtained before enrolment. Participants were randomised to LI-160 300mg daily (equivalent to hypericin 900mcg) or 300mg twice daily for 3 months. Two dosages were used to reflect different dosage regimens used across Europe. LI-160 was started one week before a target quit date (TQD). Follow-up, with support and counselling, was carried out at 1 and 3 months after the TQD. Follow-up comprised self-report of smoking abstinence verified by exhaled air carbon monoxide and saliva cotinine concentrations. The study is ongoing; primary endpoints are 6- and 12-month smoking abstinence rates.

Results

Twenty-four smokers were enrolled over the first 6 months of the study. Point prevalence smoking abstinence rates at 1 and 3 months were 20.8% and 12.5%, respectively (intention-to-treat analysis). Withdrawal rates were 46% and 58% at 1 and 3 months, respectively. Thirteen participants (54.2%) reported a total of 20 adverse events during treatment with LI-160; all but one were non-serious, transient events. Causality has not been assessed.

Conclusions

The study is ongoing. If a 6-month smoking abstinence rate similar to that seen with NRT (ie 10 to 20%) is achieved in this study, then LI-160 with individual behavioural support may be worth further investigation in an RCT.

Reference

1. Linde K, Mulrow CD. St John's wort for depression (Cochrane Review). In: *The Cochrane Library*, Issue 1 2001. Oxford: Update Software.