Efficacy of acupuncture for the prophylaxis of migraine: a multicentre randomised controlled clinical trial.

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Efficacy of acupuncture for the prophylaxis of migraine: a multicentre randomised controlled clinical trial

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Summary

Background

Our aim was to assess the efficacy of a part-standardised verum acupuncture procedure, in accordance with the rules of traditional Chinese medicine, compared with that of part-standardised sham acupuncture and standard migraine prophylaxis with beta blockers, calcium-channel blockers, or antiepileptic drugs in the reduction of migraine days 26 weeks after the start of treatment.

Methods

This study was a prospective, randomised, multicentre, double-blind, parallel-group, controlled, clinical trial, undertaken between April 2002 and July 2005. Patients who had

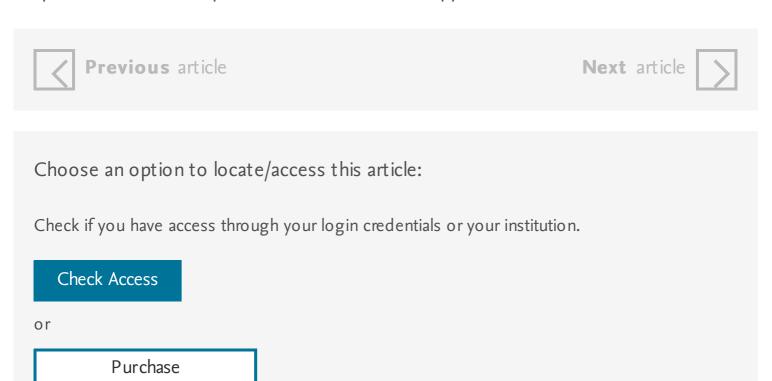
two to six migraine attacks per month were randomly assigned verum acupuncture (n=313), sham acupuncture (n=339), or standard therapy (n=308). Patients received ten sessions of acupuncture treatment in 6 weeks or continuous prophylaxis with drugs. Primary outcome was the difference in migraine days between 4 weeks before randomisation and weeks 23–26 after randomisation. This study is registered as an International Standard Randomised Controlled Trial, number ISRCT N 5268 3557.

Findings

Of 1295 patients screened, 960 were randomly assigned to a treatment group. Immediately after randomisation, 125 patients (106 from the standard group) withdrew their consent to study participation. 794 patients were analysed in the intention-to-treat popoulation and 443 in the per-protocol population. The primary outcome showed a mean reduction of 2 $\hat{A} \cdot 3$ days (95% CI $1\hat{A} \cdot 9\hat{a} \in 2\hat{A} \cdot 7$) in the verum acupuncture group, $1\hat{A} \cdot 5$ days ($1\hat{A} \cdot 1\hat{a} \in 2\hat{A} \cdot 0$) in the sham acupuncture group, and $2\hat{A} \cdot 1$ days ($1\hat{A} \cdot 5\hat{a} \in 2\hat{A} \cdot 7$) in the standard therapy group. These differences were statistically significant compared with baseline (p<0 $\hat{A} \cdot 0001$), but not across the treatment groups (p=0 $\hat{A} \cdot 09$). The proportion of responders, defined as patients with a reduction of migraine days by at least 50%, 26 weeks after randomisation, was 47% in the verum group, 39% in the sham acupuncture group, and 40% in the standard group (p=0 $\hat{A} \cdot 133$).

Interpretation

Treatment outcomes for migraine do not differ between patients treated with sham acupuncture, verum acupuncture, or standard therapy.



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