The effect of acupuncture on hot flushes: A study protocol of multi-center randomized controlled clinical trial

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Abstract

Background: Hot flushes are general postmenopausal symptoms which about 75\% of climacteric women undergo. They affect hotness, perspirations, systemic weakness, panic disorders, insomnia. Acupuncture is effective in alleviating hot flushes in practice. Assessment effectiveness and safety of acupuncture in hot flushes would be needed through multi-center trial.

Objectives: Purpose of this study is to develop the protocol of effects of acupuncture on hot flushes, a postmenopausal symptom in climacteric women.

Methods & Results: It will be a multi-centered, randomized, sham controlled, comparative trial. It will be performed by Good Clinical Practice after approval of Institutional Review Board. Selection criteria will be set according those of FDA above moderate degree. There will be a notice on concomitant medication, other herbs, dietary supplements. Superficial needling on sham points will be used for control group. Treatment period will be 8 weeks with 12 weeks' follow up. Some questionnaire scale will be used as the primary and secondary outcome.

Conclusions: The clinical trials based on this protocol will be performed.

Key words: Multi-center Trial, HotFlushes, Acupuncture