Randomized, crossover clinical trial for evaluating validity of various acupuncture device types

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Purpose: Although various placebo acupuncture devices have been developed and used in acupuncture research, there is controversy concerning whether these devices really serve as appropriate placebos for control groups. Now we are planning clinical research evaluating validity of various placebo acupuncture device types. So now we are submit abstract of the protocol.

Methods: The proposed study is a single-center prospective randomized crossover participant- and assessor-blinded trial with two parallel arms. A total of 76 participants will be randomly assigned to Group 1 or Group 2 in a 1:1 ratio. Participants will have a total of three sessions in a day with a 30-minute washout period between each session. The primary endpoint is blinding test questionnaire 1. Secondary endpoints are the Bang’s blinding index the Massachusetts General Hospital Acupuncture Sensation Scale index, and physiological data including heart rate, heart rate variability, and skin conductance response.

Results: We registered at CRIS(Clinical Research Information Service, Korea). Registration Number is KCT0001347. Now we are now recruiting participants.

Conclusion: This trial will evaluate the relevance of using placebo acupuncture devices as controls using a validation test procedure This study was supported by the Traditional Korean Medicine R&D program funded by the Ministry of Health and Welfare through the Korean Health Industry Development Institute (KHIDI) (No. H13C0700)

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Plasma metabolomics combined with personalized diagnosis guided by Chinese medicine reveals subtypes of Chronic heart failure

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Purpose: Chronic heart failure (CHF) was characterized by failure of enough blood supply from heart to meet the body’s metabolic demands, and the prevalence of CHF continuously increases globally. The personalized diagnosis of Chinese Medicine (CM) may help to stratify the CHF. CM classifies CHF into several different syndrome types, and integrating Western and Chinese medicine to treat CHF has proved a validated therapeutic approach. Metabolomics is regarded as a potential platform to provide biomarkers for disease-subtypes in recent years. In this research, we designed an explorative study of 38 patients, combining NMR plasma metabolomics with CM diagnosis in order to identify diagnostic biomarkers for two CHF syndrome subtypes.

Methods: After processing the NMR data, orthogonal partial least square discriminant analysis (OPLS-DA) was performed.

Results: The plasma metabolic patterns of group 1 ‘Yin deficiency VS non-Yin deficiency’ and 2 ‘Yang deficiency VS non-Yang deficiency’ were clearly discriminated, respectively. And potential biomarkers of CHF based on the two CM syndrome types indicated the alternative modes of metabolites and metabolic pathways in the disease, e.g. the disturbance in fatty acids, amino acids and glucose, etc.

Conclusion: This study proved that combining metabolomics with CM diagnosis can reveal metabolic signatures for CHF syndrome subtypes. The identified plasma metabolites may be of special clinical relevance for subtypes of CHF, which could lead to further understanding of mechanisms involved and an improvement in personalized interventions for CHF. This work was supported by The National Science Foundation of China(no.81302914).

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