Research Snapshots

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CHINESE HERBS IN THE TREATMENT OF INFLUENZA

OBJECTIVE: This study was designed to investigate the efficacy and safety of *Antiwei* granule, a traditional Chinese prescription, in the treatment of influenza.

METHODS: This study was designed as a multi-centre, randomised, double-blind, placebo-controlled trial. Subjects were randomised within 36 hours of onset of influenza-like symptoms; that is, fever over 37.4ºC, at least one respiratory symptom (cough, sore throat, or nasal symptoms), and at least one other symptom (headache, fatigue, myalgia, thirst, chills). Subjects received 6g *Antiwei* granule or matching placebo twice daily for three days.

Antiwei granule contained: *Ma Huang* (~11%), *Bai Mao Gen* (~33%), *Ge Gen* (~17%), *Gui Zhi* (~11%), *Gan Jiang* (~6%), *Ku Xing Ren* (~11%), *Gan Cao* (~11%).

OUTCOMES: Primary outcomes were percentage of participants who recovered after 3 days' treatment and mean symptom scores. Secondary outcomes included length of time to alleviate fever and severity of each symptom after the first 24 hours of treatment. Immunofluorescent antibody assays confirmed influenza A and B virus infection, with analysis of influenza-like and influenza-confirmed populations performed separately.

RESULTS: Four hundred and eighty adults were recruited from eight emergency departments in China. Three hundred and sixty individuals were randomised to Antiwei granule and 120 to placebo. No significant differences were observed between the two groups at baseline. Thirty-four participants withdrew, but none were due to adverse events. Influenza infection was confirmed in (50.1% in the Antiwei group and 42.1% placebo subjects. In influenza confirmed subjects (n = 225) *Antiwei* granule resulted in 23.2% recovery after 3 days (p = 0.009), compared to 6.25% in the placebo group. Similar recovery was seen in the influenza-like group (24% (*Antiwei*), 8.8% (placebo), $p < 0.001$). Compared with baseline, fever, cough and expectoration reduction improved after one-day treatmen. Other domains including chills, headache, nasal obstruction, rhinorrhoea, sore throat, fatigue and thirst were not significantly improved after one day. One adverse event was recorded with mild paroxysmal palpitations, which resolved within two days without additional treatment and the participant continued in the study.

CONCLUSION: Oral administration of 6g *Antiwei* granules twice daily for three days was associated with improvement in total symptom scores and patient recovery from influenza-like and influenza-confirmed populations. Generally *Antiwei* granule was well tolerated by participants with only one adverse event.

COMMENT: Overall, the reporting for this trial complies with the CONSORT statement. However, some parameters were not elaborated, including characteristics of the herbal products (methods for authentication, analysis, purity, standardisation and heavy metal testing). The authors acknowledge the limitations in design, including no follow-up and short duration of observation. The positive results should be interpreted with some caution.

Wang L, Zhang RM, Liu GY, Wei BL, Wang Y, Cai HY, et al. Chinese herbs in treatment of influenza: A randomized, double-blind, placebo-controlled trial. Respiratory Medicine. 2010;104(9):1362–9.

GINSENG FORMULAE FOR CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD): A SYSTEMATIC REVIEW

OBJECTIVE: This review focuses on evaluating Ginseng formulae for stable COPD.

METHODS: The authors searched four English and three Chinese databases to identify randomised control trials (RCTs). Methodological quality of studies was assessed using Jadad's scale and Cochrane risk of bias. COPD, ginseng and their related synonyms were searched and details extracted. Selected studies met pre-specified criteria, including; RCTs (with or without blinding); participants with stable COPD; and studies administering oral formulae with ginseng being one ingredient compared to a control group. Included studies also needed to report at least one of four primary outcome

measures: (1) Spirometric parameters; (2) Percentage of effectiveness of symptom changes; (3) Quality of life; or (4) Frequency of COPD exacerbations.

RESULTS: Twelve studies with a total of 1560 stable COPD patients met the selection criteria for this review. Eleven studies were published in Chinese and one in English. Duration of intervention ranged from one month to six months, with three studies using a follow-up period (six months). All studies used different ginseng formulae, containing between one and 12 Chinese herbal ingredients. Methodological weakness was observed in the majority of studies, with only one study being considered as of low risk of bias. Results differed throughout the studies, yet encouraging evidence of some effect in improving lung function (FEV1), respiratory symptoms and quality of life was reported.

CONCLUSION: The authors observed some benefit of ginseng formulae for stable COPD. Due to methodological weaknesses in the included studies, further trials are needed to address the identified problems in this review.

COMMENTS: The data from this review suggest some effect of ginseng formulae stable COPD. However, poor methodologies need to be addressed in further studies to confirm ginseng formulae's true effect on this population.

An X, Zhang AL, Yang AW, Lin L, Wu D, Guo X, et al. Oral ginseng formulae for stable chronic obstructive pulmonary disease: A systematic review. Respiratory Medicine. 2011;105(2):165–76.

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BU ZHONG YI QI TANG FOR LONG-TERM MANAGEMENT OF QI DEFICIENT ATOPIC DERMATITIS PATIENTS

OBJECTIVES: To evaluate the efficacy and safety of *Hochu-ekki-to* (*Bu Zhong Yi Qi Tang*) in the long-term management of *Kikyo* (qi deficient) patients with atopic dermatitis (AD) via a multicentre, double-blind, randomised, placebo-controlled trial.

METHODS: *Kikyo* condition was assessed using a questionnaire scoring system. Ninety-one AD patients aged 20–40 were enrolled. Patients who were using weak topical steroids, strongest topical steroids, systemic steroids, oral suplatast tosilate, allergen desensitisation therapy or other herbal medicines for less than four weeks before the study were excluded. An independent investigator randomly assigned patients to the *Hochu-ekki-to* treatment or placebo group. Patients received twice daily of either *Hochu-ekki-to* fine granules or placebo granules for 24 weeks, while continuing their usual treatment regime of topical steroids/tacrolimus, emollients or oral antihistamines.

OUTCOME MEASURES: Skin severity scores, total equivalent amount (TEA) of topical agents used, adverse effects and laboratory examinations were examined at pre- (0-week), mid- (12-week) and post- (24-week) treatment. Prominent efficacy rate and aggravated rate were also evaluated.

RESULTS: Seventy-seven patients completed the trial (Hochu-ekki-to: n = 37; placebo: n = 40). There was no significant difference in overall skin severity score. The use of TEA of topical agents and aggravated rate (ratio of patients whose TEA had increased over 50% at 24 weeks) were significantly (P < 0.05) lower in the *Hochu-ekki-to* group. Prominent efficacy rate (rate of patients whose severity score became 0 at the end of study) was 19% in the *Hochu-ekki-to* group and 5% in the placebo group (P = 0.06). Mild adverse events (53 events in total) were reported; however there were no significant differences in adverse events and laboratory examination (serum IgE, lactate dehydrogenase (LDH) and eosinophil counts) results between both groups.

CONCLUSION: The authors concluded that *Hochu-ekki-to* could reduce the usage of topical steroids/tacrolimus without aggravating AD and be a useful adjunct to conventional treatments for *Kikyo* patients with AD.

COMMENTS: The questionnaire scoring system was not explained in depth and there was no indication that the reliability and validity of the scoring system was tested, therefore it is difficult to determine if the questionnaire scoring system was sufficient for the diagnosis of *Kikyo* condition.

Kobayashi H, Ishii M, Takeuchi S, Tanaka Y, Shintani T, Yamatodani A, Kusunoki T, Furue M. Efficacy and Safety of a Traditional Herbal Medicine, Hochu-ekki-to in the Long-term Management of Kikyo (Delicate Constitution) Patients with Atopic Dermatitis: A 6-month, Multicenter, Double-blind, Randomized, Placebo-controlled Study. Evidence-based Complementary and Alternative Medicine 2010;7(3):367–73.

ACUPUNCTURE CAN REDUCE TYPE I HYPERSENSITIVITY ITCH IN ATOPIC ECZEMA PATIENTS

OBJECTIVES: To evaluate the effects of acupuncture on type I hypersensitivity itch and on the wheal and flare formation in atopic eczema (AE) patients in a double-blinded, randomised, placebo-controlled, crossover trial.

METHODS: An allergen stimulus (grass pollen or house dust mite) was applied to 30 AE patients. To test the direct

effect of acupuncture, the patients were randomised to receive verum acupuncture (VA) on LI 11 *Quchi* and SP 10 *Xuehai*, 'placebo-point' acupuncture (PA), or no acupuncture (NA) four minutes after stimulus application. Those in the VA and PA group received one session of acupuncture for 11 minutes. To assess the preventative effect, the allergen stimulus was applied again after a resting period of 15 minutes. A visual analogue scale (VAS) was used to measure the severity of itch after each application of the allergen stimulus. Ten minutes after each allergen application, wheal and flare sizes and skin perfusion were measured. The Eppendorf Itch Questionnaire (EIQ) was answered by patients 15 minutes after intervention and also after the second allergen stimulus was applied. The study was designed as a three-arm crossover trial where each patient was subjected to all three groups and each served as its own control.

RESULTS: Direct effect: Compared with PA and NA, VA had mean VAS-ratings and mean descriptive ratings of EIQ which were significantly lower; mean wheal sizes were significantly smaller in VA than NA while mean flare sizes were significantly smaller in VA than PA; mean perfusion units were significantly lower in VA than NA. Preventative effect: Compared to PA and NA, VA had mean VAS-ratings, mean wheal and flare sizes and mean EIQ ratings which were significantly lower; mean perfusion units were significantly lower in VA than NA.

CONCLUSION: It was concluded that type I hypersensitivity experience by AE patients could be effectively reduced with verum acupuncture treatment when compared with placebo-point treatment or no treatment.

COMMENTS: The design of the study as a three-arm crossover trial was not explained in depth. It was stated that patients were subjected to all groups but it was not stated how this was carried out. There was no mention of the intervals between each intervention during the crossover and whether precautions were taken to prevent influence from the effects of the previous intervention on the results of the next intervention applied to patients. Furthermore, this study reflected mainly on the immediate result of a single acupuncture treatment and did not mention the extent/duration of the effects and if it could be applied for long-term management.

Pfab F, Huss-Marp J, Gatii A, Fuqin J, Athanasiadis I, Irnich D, Raap U, Schober W, Behrendt H, Ring J, Darsow U. Influence of acupuncture on type I hypersensitivity itch and the wheal and flare response in adults with atopic eczema – a blinded, randomized, placebo-controlled, crossover trial. Allergy 2010;65(7):903–10.

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