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Clinical Trial for Anti-hepatofibrotic Efect of a Traditional Korean Formula (CGX) in Patients with Chronic Liver Disease

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Purpose: CGX is a modification of a traditional Korean herbal medicine, which is under clinical trial phase III for hepatofibrosis therapeutic effect. The objective is to present the status for CGX development regarding its clinical backgrounds, pharmacological studies in animal models, and current process of randomized clinical trial.

Methods: CGX has been used for patients suffering various liver diseases, including chronic viral hepatitis and alcoholic liver disorders. The safety of CGX was evaluated in animal-based repeated toxicological studies using rats and beagle dogs. The pharmacological actions against hepatic fibrosis were evidenced in various chronic liver injury animal models using chemicals (CCl4, DMN, or TAA), chronic alcohol consumption, choline-deficient (MCD) diet, and bile duct ligation (BDL) respectively. It is now under a randomized controlled clinical trial.

Results: The total number of participants is 174 in 2 Hospitals, who are suffering from chronic HBV, HCV or Alcoholic liver disease. The inclusion criteria is patients with LSM 5.5 kPa to 16 kPa, aged between 18–75 year. The exclusion criteria is the conditions of too severe status as follows: ascites, esophageal varix, TB > 3 mg/dl, AST, ALT > ULN > 5 folds, INR > 2.0 or platelet < 80,000/mm3 and BMI > 30. The drug treatment period is 6 months for 3 groups (placebo, 1gram or 2 gram of CGX daily). The primary measurement is the changed value of LSM (liver stiffness measurement) during 6 months, and the secondary measurements are the changed value of hyaluronic acid (HA), serum TGF-β1, PDGF, AST to platelet ratio index (APRI) and QOL (SF-36) respectively.

Conclusion: It is expected that multi-sites clinical trial evidences the fibro-therapeutic effects of CGX in patients with chronic viral or alcoholic liver diseases.

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Chinese herbal medicine modified Yu ping feng San Formula for treatment of Allergic Rhinitis in Children: a systematic review

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Purpose: Modified Yu ping feng san Formula is widely applied for allergic rhinitis in children in China. Many clinical trials are reported. This study assessed the efficacy and safety of modified Yu ping feng san Formula for the treatment of allergic rhinitis in children.

Methods: PubMed, Cochrane CENTRAL, and four Chinese databases were searched through July 2014. We included randomised controlled trials (RCTs) that tested modified Yu ping feng san Formula for allergic rhinitis in children, compared with no intervention, placebo, pharmaceutical medication. Authors extracted data and assessed the quality independently. We applied RevMan 5.2.0 software to analyse data of included randomised trials.

Results: A total of 13 RCTs involving 1177 participants were identified. The methodological quality of the included trials was generally poor. Meta-analyses of two trials demonstrated that modified Yu ping feng san Formula were more effective than pharmaceutical medication alone in improving nasal symptoms and clinical signs (RR 0.67, 95% CI 0.46 to 0.97). Meta-analyses of two trials demonstrated that modified Yu ping feng san Formula plus pharmaceutical medication were more effective than pharmaceutical medication alone in improving nasal symptoms and clinical signs (RR 0.78, 95% CI 0.62 to 0.97). Meta-analyses of three trials demonstrated that modified Yu ping feng san Formula plus pharmaceutical medication were more effective than pharmaceutical medication alone in controlling recurrence of allergic rhinitis in one year after drug withdrawal (RR 0.62, 95% CI 0.52 to 0.75). No serious adverse events were reported.

Conclusion: The modified Yu ping feng san Formula appears to have additional benefit based on pharmaceutical medication treatment in improving nasal symptoms and clinical signs and recurrence of allergic rhinitis. However, due to high risk of bias of the trials, we could not draw confirmative conclusions on its benefit. Future clinical trials should be well-designed and avoid the issues that are identified in this study.

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