

**Title:** Measuring the Efficacy and Safety of Chinese Herbal Medicine in Treating Seasonal Allergic Rhinitis (SAR)

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### **Abstract**

**Background:** Seasonal allergic rhinitis (SAR) is one of the most commonly encountered diseases in Europe, affecting about 20% of the general population. Current Western medical treatment with various anti-allergy drugs and immunotherapy often fails to be effective, may cause adverse effects or has to be administered for several years. Hence, a growing number of patients use complementary and alternative medicine (CAM), such as Chinese herbal medicine (CHM).

**Objective:** The efficacy and safety of individualized CHM prescriptions given as Hydrophilic concentrate<sup>®</sup> (HC) solutions were measured, and compared with the efficacy of antihistamine drugs in SAR patients. Additionally, the onset and duration of improvement from CHM were measured and the efficacy of CHM in patients with normal and elevated Immunoglobulin E (IgE) levels compared.

**Design:** Parallel-group clinical trial, 1-week baseline period followed by 4-week treatment period.

**Setting:** Private clinic for Chinese medicine.

**Patients:** 25 patients with SAR.

**Interventions:** 20 patients received individualized CHM prescriptions as HC and 5 patients received antihistamine medication.

**Outcome Measures:** The primary outcome measure was a 10 cm visual analogue scale (VAS) to be marked by all patients assessing the severity of SAR symptoms for the last 7 days at the end of the baseline and the end of the treatment period. Secondary outcome measures were the validated Allergic Rhinitis Symptom Questionnaire (ARSQ) and the Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ); additionally patients kept a Relief medication diary and an Adverse-event diary. A Global Assessment of Change Scale (GACS) to assess differences in SAR symptom severity in contrast to previous years had to be completed at the end of the trial. Outcome measurements were evaluated against local pollen counts.

### **Results:**

CHM group: The VAS and Relief medication score improved but not with statistical significance, in contrast ARSQ and RQLQ endpoints scores improved with statistical significance and highly statistical significance respectively. The comparison of ARSQ baseline and weekly score showed a gradual improvement over the first three weeks of treatment. In the fourth week only eye symptom scores decreased further, nose and sinus symptom scores increased slightly. Treatment was equally efficacious for patients with normal and elevated IgE levels. Liver and kidney functions were not impaired and only mild adverse events were reported.

CHM group - antihistamine group: VAS baseline scores showed a statistically significant difference, and can thus not be used to compare efficacy of treatment. ARSQ and RQLQ endpoints scores revealed no difference between the two groups, ARSQ eye and sinus, RQLQ non-nose/eye problems and GACS were in favour of the TCM group.

**Conclusions:** On the background of the serious limitations of this trial - small sample size, unequal severity of SAR symptoms - results can only be seen as showing a certain tendency. Individualized CHM prescriptions administered as HC seem to alleviate symptoms in patients with mild SAR without causing serious adverse events. Onset of effect was gradual and a possible deterioration of effect for nose and sinus symptoms was recorded after 3 weeks. Results suggest that CHM are as efficacious as antihistamine treatment.

Further studies with more participants are needed to compare the efficacy of standardized and individualized CHM treatment as well as the effect of single herbs and herbal combinations on individual symptoms. Heat symptoms were frequently encountered, TCM theory should be revised with regard to the underlying patterns of SAR.