Background: We report on the study design and protocol of a randomised controlled trial (Acupuncture in Seasonal Allergic Rhinitis, ACUSAR) that investigates the efficacy of acupuncture in the treatment of seasonal allergic rhinitis (SAR). Objective: To investigate whether acupuncture is non-inferior or superior to (a) penetrating sham acupuncture and (b) rescue medication in the treatment of SAR. Design: 3-armed, randomised controlled multi-centre trial with a total follow-up time of 16 weeks in the 1st year and 8 weeks in the 2nd year. Setting: 41 physicians in 37 out-patient units in Germany specialised in acupuncture treatment. Patients: 400 seasonal allergic rhinitis patients with clinical symptoms and test-positive (skin-prick test and/or specific IgE) to both birch and grass pollen. Interventions: Patients will be randomised in a 2:1:1 ratio to one of three groups: (a) semi-standardised acupuncture plus rescue medication (cetirizine); (b) penetrating sham acupuncture at non-acupuncture points plus rescue medication; or (c) rescue medication alone for 8 weeks (standard treatment group). Acupuncture and sham acupuncture will consist of 12 treatments per patient over 8 weeks. Main Outcome Measures: Average means of the Rhinitis Quality of Life Questionnaire (RQLQ) overall score and the Rescue...
Medication Score (RMS) between weeks 6 and 8 in the first year, adjusted for baseline values.
Outlook: The results of this trial available in 2011 will have a major impact on the decision of whether acupuncture should be considered as a therapeutic option in the treatment of SAR.

Stichworte:
Acupuncture; Traditional Chinese medicine; Complementary and alternative medicine; Allergy; Seasonal allergic rhinitis; Randomised controlled trial

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