

## P–③–2

### Clinical study of a novel TCM therapy concept for atopic dermatitis: Combined efficacy of three novel herbal formulas Kujin-Plus I-III

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In the present open-label clinical trial, the efficacy and safety of a new TCM / Kampo multi component therapy approach for atopic dermatitis (AD) was investigated. Therefore, 94 AD patients received the formula Kujin-Plus-I orally, combined with both the skin lotion Kujin-Plus-II, and the ointment Kujin-Plus-III. Each of the below mentioned plant drugs was extracted with boiling water for 5 h, concentrated and reworked into the respective formulation. Standardised scores were used for evaluating the severity of the disease (clinical score; 0-4) and the severity of pruritus (pruritus score; 0-4) with both scores having significantly improved at the end of treatment ( $P < 0.01$ ; nonparametric test) after twelve months. Blood eosinophil-ratio and serum IgE-levels, which were elevated in AD patients, were significantly reduced at the end of therapy ( $P < 0.001$ ). Of 94 AD patients treated with Kujin-Plus, 32 were markedly improved, 59 were improved, 3 were slightly improved with no case of ineffective treatment. There was no hint of renal or hepatic toxicity or of any other adverse effects. The significant reduction in both blood eosinophil-ratio and serum IgE-level thus confirms that the Kujin-Plus therapy concept is clinically efficacious on otherwise intractable AD.

Kujin-Plus-I: *Sophora flavescens*, *Polygonum cuspidatum*, *Isatis tinctoria*, *Smilax glabra*, *Angelica dahurica*, *Glycyrrhiza uralensis*, *Scutellaria baicalensis*, *Chrysanthemum indicum*, *Prunella vulgaris*, *Oldenlandia diffusa*. Kujin-Plus-II: *Sophora flavescens*, *Coptis chinensis*, *Scutellaria baicalensis*, *Stemona sessilifolia*, *Punica granatum*, *Chrysanthemum indicum*, *Paris polyphylla*. Kujin-Plus-III: *Sophora flavescens*, *Polygonum cuspidatum*, *Isatis tinctoria*, *Angelica dahurica*, *Glycyrrhiza uralensis*, *Scutellaria baicalensis*, *Citrus × limon*, *Dryobalanops aromatica*.