

## Clinical Evaluation of Japanese Phytotherapy (Gosha-jinki-gan) in Diabetic Neuropathy: A Prospective Open Pilot Study

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**Objective:** Diabetic neuropathy is one of the severest and most common complications of diabetes mellitus. Direct therapeutic options are still limited. In Japan, a traditional prescription of ten East Asian medicinal herbs, Gosha-jinki-gan, has shown empirical efficacy for this indication which was confirmed in clinical trials. Pharmacological research using animal models revealed that Gosha-jinki-gan influences the metabolic situation as an aldose reductase inhibitor, works analgetic and improves the microcirculation of peripheral nerves. We here present data of the first clinical trial conducted with a standardized phytoproduct (TJ-107) of this regimen in Europe according to ICH-GCP guidelines.

**Materials and Methods:** 25 diabetic patients (DM type 1 and 2, HbA<sub>1c</sub>  $\leq$  9, mean age 60.5 ( $\pm$ 9)) complaining about a symptomatic stage of diabetic neuropathy with the leading symptoms paresthesia, numbness, or pain were enrolled in a prospective open treatment trial. Total observation period was 36 weeks with a treatment phase of 24 weeks and a follow-up phase of 8 weeks. Primary endpoints were changes in neuropathic symptoms and nerve conduction velocity (NCV). Secondary endpoints were changes in neuropathic deficits, quantitative sensory and autonomic testing, evaluation of microcirculation, Quality of Life and metabolic parameters.

**Results:** Descriptive statistics were applied for simple data, ANOVA for continuous variables. A significant improvement of clinical symptoms by 52.5% was found applying a validated symptom score. There were no such changes for NCV. Evaluation of temperature and vibration sensation resulted in noteworthy, in part significant improvement. No clear change was observed for cardiac and gastric autonomic neuropathy, and microcirculatory testing. Quality of Life showed a trend towards improvement. After stopping the treatment, the symptoms aggravated again which was reflected in most test results after the follow-up phase.

**Conclusions:** In this pilot study with a limited Western study population and relatively short time range, noteworthy evidence was obtained that Gosha-jinki-gan (TJ-107) is a safe, tolerable and efficacious treatment for symptomatic stages of diabetic neuropathy. In five out of eight endpoints a remarkable or even significant improvement was demonstrated. Future results of a controlled clinical study will confirm if this herbal medication opens up a new therapeutic option for diabetic neuropathy within an international context.