Acupuncture for diabetic peripheral neuropathy in patients with diabetes mellitus type 2 - two-armed randomised controlled trial

Summary:
Objective: The primary study objective is to assess the effectiveness of a series of acupuncture treatment plus routine care for adult patients suffering from symptoms of diabetic peripheral neuropathy (DPN) in comparison to a group with routine care alone (control group) in regard to its impact on pain and overall DPN-related complaints.

The secondary study objective is to assess the effect of acupuncture on disease specific and general parameters.

Design: Two-arm, open-label, randomised controlled multicenter trial.

Participants: 110 participants (18-70 years old) suffering from DPN

Intervention: The participants of the intervention group (n=55) are given 12 acupuncture treatments of 20-30 minutes each, over the course of 8 weeks. The participants of the control group (n=55) are first only observed over 16 weeks; during this observation period they receive 3 neurological exams and questionnaires. In week 16 they are offered the acupuncture series for free.

All participants can continue their medication they have been prescribed to treat pain or discomfort related to DPN before the participated in the trial, or they can even get new prescriptions from their physician to treat DPN-related pain or discomfort during the trial.

Outcome parameters: after 6, 12 and 26 weeks after study inclusion the function of N. suralis will be assessed with electrophysiological measurements; experienced pain and the overall DPN-related discomfort will be registered on each a visual analogue scale (VAS, 0-100mm); further assessment of subdimensions of neuropathic pain employing specific and validated questionnaires, such as: Neuropathic Pain Symptom Inventory (NPSI) and Diabetic Peripheral Neuropathic Pain Impact Measure (DPNPI), drug/ pain-killer consumption and safety are further parameters that will be registered.

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