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Efficacy and safety of Shenyankangfu tablets for primary glomerulonephritis: Study protocol for a multicentre, prospective, double-blind, double-dummy, randomized controlled clinical trial

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Background: Chronic kidney disease is a common and frequently occurring disease, and most chronic kidney diseases have evolved from the primary glomerulonephritis. Proteinuria is an independent risk factor for chronic kidney disease progression, thus reduction of proteinuria is extremely important to improve the prognosis of chronic kidney disease. General consensus is that the therapy for decreasing proteinuria ought to apply steroids and/or immunosuppressants, angiotensin converting enzyme inhibitors and angiotensin-II receptor blockers, but side effects and adverse reactions reduce partial patients' benefit and even cause harm. Meanwhile, the expenses of these drugs are relatively high and become economic burden for most Chinese patients; therefore, seeking out other cheap and effective drugs for decreasing proteinuria is urgently needed. In China, Shenyankangfu Tablets are widely applied Chinese patent medicines for many years which have demonstrated excellent efficacy and safety on decreasing proteinuria, but it has a lack of evidence from evidence-based medicine. Therefore, we have designed the present randomized controlled clinical trial aiming to evaluate the efficacy and safety of Shenyankangfu Tablets for controlling the proteinuria of patients with primary glomerulonephritis compared with losartan potassium.

Methods/Design: The present study is a multicentre, prospective, double-blind, double-dummy, randomized controlled clinical trial. The present study will enroll 720 patients diagnosed with primary glomerulonephritis, blood pressure ≤140/90 mmHg, estimated glomerular filtration rate ≥45 ml/min/1.73m2, 0.5g≤24-hour proteinuria ≤3.0 g, traditional Chinese medicine syndrome conform Qi-Yin Deficiency in 43 sites. The eligible patients will be at 1:1:1:1:1 ratio randomly divided into Shenyankangfu Tablets group, losartan potassium 50 mg group, losartan potassium 100 mg group, Shenyankangfu Tablets plus losartan potassium 50 mg group and Shenyankangfu Tablets plus losartan potassium 100 mg group. All groups will be followed up for 48 weeks and the seven visits will be performed in week 0, 4, 8, 12, 24, 36, 48. The primary efficacy outcome is change of 24-hour proteinuria after treatment; the secondary efficacy outcomes include changes of serum creatinine, estimated glomerular filtration rate, traditional Chinese medicine syndrome score and serum albumin after treatment. Adverse events will be monitored throughout the trial.

Discussion: The result of the trial will provide solid evidence of evidence-based medicine to evaluate the efficacy and safety of Shenyankangfu Tablets for controlling the proteinuria of patients with primary glomerulonephritis compared with losartan potassium. Moreover, we infer that Shenyankangfu Tablets plus losartan potassium therapy can decrease proteinuria to relatively large extent compared with Shenyankangfu Tablets therapy alone or losartan potassium therapy alone.

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