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EFFECT OF DIACEREIN IN RENAL FUNCTION, METABOLIC CONTROL, AND INFLAMMATORY MARKERS IN TYPE 2 DIABETIC PATIENTS WITH NEPHROPATHY

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Background: Chronic inflammation seems to be involved in the pathogenesis of the diabetic nephropathy (DN) and anti-inflammatory agents have been suggested as adjuvant treatment. Diacerein is anthraquinone derivative, which inhibits the synthesis of interleukin-1 and TNF-α, and can be an alternative to the anti-inflammatory agents.

Objective: To evaluate the effect of Diacerein on inflammatory markers in patients with type 2 diabetes mellitus (T2DM) with DN.

Methods: A randomized clinical trial placebo-controlled, double-blind, with parallel groups was designed to enroll T2DM patients, aged 30 years or older, with DN. Patients with fasting blood glucose ≥126 mg/dl, A1C between 7.5-10%, using oral anti-diabetic agents or insulin will be eligible whether had DN confirmed by albuminuria and/or chronic kidney disease (GFR >60 ml/min). Patients with chronic inflammatory diseases, pancreatitis, hypersensitivity to renin derivatives, on use of anti-inflammatory agents or pioglitazone will be excluded. Patients will be assigned using a software (Random Allocation Software) in random blocks. They will be allocated to Diacerein (50 mg) or Placebo in the morning and evening, according to three different schemes: 1: Placebo+Placebo; 2: Diacerein+Placebo; 3: Diacerein+Diacerein, and followed-up for 90 days. The sample size calculation was based on estimate assuming a 16% reduction in the proteinuria level between groups, with an alpha of 0.05 and power of 80%, resulting in 23 patients per group. The protocol was registered in the Plataforma Brasil; the Research Ethics Committee approved the protocol and all patients will sign a consent form. The study was supported by CNPq, Universidade de Passo Fundo, and laboratory TRB PHARMA, which will provide Diacerein and placebo.

Results: We identified 600 potentially eligible patients, from the outpatient clinic of School of Medicine of the University of Passo Fundo. A pilot study was conducted to test the instruments and procedures for implementation of the study, which will enroll patients from August 2013 to January 2014, and will assess the outcome until March 2014.

Conclusions: The details of the project and approval of regulatory agencies have been made in the last 10 months, while the funding was requested 14 months ago. Now all requirements are ready to start.

★ **2º lugar**