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EFFECT OF DIACEREIN ON METABOLIC CONTROL AND ACUTE INFLAMMATORY PARAMETERS IN PATIENTS WITH TYPE 2 DIABETES TREATED WITH ANTI-HYPERGLICEMIC DRUGS – A STUDY PROTOCOL FOR A RANDOMIZED CONTROLLED TRIALTres GS^{1,2}, Piovesan F^{1,2}, Fuchs SCC¹, HRK Lisboa², Palma ME², Fuchs FD¹, Moreira LB¹¹Postgraduate Program in Cardiovascular Science, UFRGS, Cardiology Division, Hospital de Clínicas de Porto Alegre; ²UPF, Passo Fundo, RS, Brazil.

Background: Inflammatory mediators have a role in the pathogenesis of obesity and insulin resistance. Adipocytes express pro-inflammatory cytokines such as TNF- α , IL-1 β , IL6 causing β -cell apoptosis, decrease insulin secretion and increase resistance resulting in hyperglycemia. The IL-1 β has been a therapeutic target for preserving the β cell mass and its function. The Diacerein, used in the treatment of osteoarthritis, is a derivative of anthraquinone that inhibits IL-1 β and TNF- α and may be a new therapeutic option for type 2 diabetes mellitus (T2DM).

Objectives: To evaluate the effect of diacerein on glycemic control (fasting blood glucose, glycosylated hemoglobin (A1C)) and inflammatory mediators in patients with T2DM.

Methods: This placebo-controlled, double-blind, parallel group randomized clinical trial will include T2DM patients, ≥ 30 years old, A1C between 7.5% and 10%, treated with oral hypoglycemic drugs and/or insulin without microalbuminuria and/or nephropathy. The exclusion criteria are use of pioglitazone, chronic inflammatory diseases, pancreatitis, liver disease, or hypersensitivity to rhein and anthraquinone derivatives, pregnancy and lactation. Patients will be randomly assigned (Random Allocation Software) to three groups: Group A: diacerein 50mg + placebo; Group B: diacerein 50mg + diacerein 50 mg and Group C: placebo + placebo in the morning and at night respectively. Follow up will be conducted in seven, 30, 60 and 90 days. For a delta in A1C of 1.5%, it was estimated that a sample of 23 subjects for each group would provide alpha of 0.05 and power of 80%. The study was approved by institutional review board and is funded by CNPq, receiving support from Passo Fundo University. Diacerein and placebo will be provided by TRB PHARMA.

Results: We identified 600 potentially eligible patients from outpatient clinic of the Medicine School (University of Passo Fundo). A pilot study was conducted to test instruments and aiming staff training. It is planned to include patients from August 2013 until January 2014.

Conclusion: We presented the study protocol for a randomized controlled trial aiming to test the effect of diacerein over metabolic controls and inflammatory mediators in patients with DM2.