( ) R1 ( ) R2 ( ) R3 (X) PG0 ( ) PG1 ( ) Estagiário ( ) Tecnólogo ( ) PIBIC

Last Name - Mitne
First Name - Somaia
Middle -

Service (sector)
Retina and Vitreous

Nº CEP
644/06

(Comitê de Ética em Pesquisa da Universidade Federal de São Paulo– UNIFESP)

EFFECTS OF COPAXONE IN THE NERVE FIBER LAYER THICKNESS AND RETINAL FUNCTION IN DIABETIC PATIENTS AFTER PAN-RETINAL PHOTOCOAGULATION, A DOUBLE-MASKED RANDOMIZED CLINICAL TRIAL.

S. Mitne, S.H. Teixeira, L. Nóia, N.S. Moraes, M.E. Farah, A. Paranhos Jr.

Purpose: To evaluate the neuroprotective effect of Copaxone (Glatiramer acetate, COP, Copolymer-1) injections in the nerve fiber layer thickness and retinal function in diabetic patients who underwent panretinal photocoagulation (PRP).
Methods: Twenty seven patients (49 eyes) with severe nonproliferative or early proliferative diabetic retinopathy and no previous laser treatment were enrolled. They were divided into two groups: A which received Copaxone or B which received mannitol (placebo) using a block randomization. Both drugs were offered by subcutaneous administration one week prior and in the three sections of PRP, one per week. All patients received a full ophthalmic examination (best-corrected Log-Mar visual acuity, slit lamp examination, applanation tonometry, fundus biomicroscopy and indirect fundus examination); functional examination (Humphrey 24-2 SITA STANDARD visual field, Eletroretinograms and FDT C-20 strategy visual field) and anatomic examination (Color fundus photography and fluorescein angiography, GDX-VCC, Optical Coherence Tomography (OCT) and Heidelberg Retinal Tomography (HRT) according to the chronogram table above:

Exams		Pre PRP	1st month	3rd m.	6th m.	1 yr.
Functional Exams	VA (log-Mar)	+	+	+	+	+
	SAP	+	+	+	+	+
	FDT	+	+	+	+	+
	ERG	+			+	
	OCT	+	+	+	+	+
	HRT	+	+	+	+	+

Anatomic Exams	GDx-VCC	+	+	+	+	+
	Color fundus photography	+				+

On the baseline evaluation, qui-squared test will be used for categorical variables evaluation (sex, race, retinopathy grade). Student bi-tailed t test for independent variables, will be used when analyzing continuous variables (age, visual acuity, MD of SAP and FDT). To compare two groups, a two-way variance analysis test for repeated measurements will be used. All the probabilities (p-values) will be considered statistically significant as they reach values lower than 0.05.

Results: Since the study is on going, and it is a double masked randomized controlled clinical trial, we are presenting the baseline results comparing groups A and B. The inclusion phase was successfully achieved. The epidemiological analyses before treatment showed no differences between groups concerning sex (Chi-Square = 0.33; p = 0.57), age (Group A: 51.7 ± 8.9; Group B: 56.7 ± 10.9; p=0.21), time of diabetes (Group A: 14.4 ± 6.8; Group B: 13.1 ± 4.3; p=0.56), and initial serum glucose level (Group A: 197.7 ± 92.2; Group B: 212.6 ± 47.1; p=0.67).

Conclusion: There are no significant differences regarding baseline data between groups A and B.