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Randomized controlled clinical trial open to 24 weeks of efficiency and safety in outpatient with obesity grade I and II treated with Clobenzorex vs. Clobenzorex with melatonin

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Introduction: Obesity is a disease characterized by the excess of adipose tissue (fat) in the body. Such disease is determined in adult persons when there is a Body Mass Index (BMI) is equal or higher than 30 kg/m^2.

Purpose: To evaluate the efficacy and safety of Clobenzorex 60 mg/Melatonin 3 mg (morning or night) against to Clobenzorex 60 mg in Mexicans with exogenous obesity during 24 weeks.

Methodology: It was a longitudinal, prospective and comparative study. This study was conducted under 180 exogenous obese patients, administered: (1) Treatment "A" (Clobenzorex 60 mg/Melatonin 3 mg 1 capsule VO, morning), (2) Treatment "B" (Clobenzorex 60 mg/capsule VO Melatonin 3 mg one night) or (3) Treatment "C" (60 mg 1 capsule Clobenzorex VO, morning). Efficacy was evaluated by weight loss (kg), BMI, waist-to-hip ratio (WHR) and percentage of body fat. On the other hand safety was evaluated by recording adverse events occurred.

Results: The treatment "A" causes polydipsia, xerostomia and headache, treatment "B" had a safety advantage for shorter duration and number of adverse events. Finally, "C" treatment compared to "A" and "B"" treatment, had the lowest rate of adverse effects by causing only one, which could be polydipsia, headache or constipation.

Conclusion & Significance: All treatments were clinically effective. Greater reduction of the WHR and waist circumference was observed when using Clobenzorex. However, Clobenzorex/Melatonin (night) resulted safer due to the lower number and duration of adverse events.

Biography

Pamela Georgina Avila Lamadrid is currently a Medical student of Superior School of Medicine (Escuela Superior de Medicina) at Instituto Politecnico Nacional, Mexico. She is a Junior Researcher who has been working at the Obesity Center of the School since 2016 on different research lines regarding obesity, diabetes, fatty liver, metabolic syndrome and hypertension. Her most important recent research is focused on drug effectiveness and security for obesity and fatty liver treatment.

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