#0091

Effectiveness and Safety of an Adjuvant Phytoformula in the Treatment of Patients with Type 2 Diabetes Mellitus.

Author(S)

Nidia Angélica García Espinoza, DACM (1), Hugo Morales Tello, DACM (1), Ricardo Sacchi Córdova, BS (1), Nicasio Morales Sarabia, BS (1), Jair Isaí Ortega Gaxiola, PhD (1), José Alfredo Primelles Gingele, BS (1), María Magdalena Valencia Gutiérrez, MD, MPH (2), Erick Ayala Calvillo, PhD (3), *Cesar Ochoa Martinez, MD, PhD (4).

Organizations/Affiliations:

(1) SAPI de C.V. – División Elevate® (2) Escuela Superior de Medicina, Instituto Politécnico Nacional, CDMX, México, Especialista en Medicina Familiar IMSS/UNAM. (3) Facultad de Farmacia, Universidad Autónoma del Estado de Morelos. Cuernavaca, Morelos, México. (4) Center for Clinical Research, WesternU Medical Center at Western University of Health Sciences, Pomona, CA, USA.

Abstract

Introduction: I hereby inform you that the design of the study was adjusted to a clinical trial, since it meets the characteristics, the sample size was determined according to the article: Antidiabetic property (Moringa oliefera) leaf tablets by V. Veeraman Arun Giridhari from 2011, which was performed in patients with type II diabetes, Considering their changes in glycated hemoglobin, the data were applied to the mean difference formula, which indicates that 31 patients per group is enough to reach a statistical power of 80% with 95% CI. In the case of the present study, the population is sufficient to show statistically significant differences with sufficient power. When we searched studies for the rest of the compounds, was limited to studies in animal models, because of this finding we did not consider them, and they also show smaller sample sizes.

Background: Type 2 diabetes mellitus (T2DM)) is a "metabolic disorder of multiple etiology characterized by chronic hyperglycemia with alteration of carbohydrate metabolism, fat and proteins as a result of defects in insulin secretion, insulin action or both".(1) T2DM has been a public health problem associated to comorbidities and mortality.(2) Therefore, Terrabrio SAPI de CV developed the phytoformulation Elevaté® with several natural products [Shilajit *(Asphaltum punjabianum)* Chaga *(Inonotus obliquus),* Moringa *(Moringa oleífera),* Berberina *(Berberina vulgaris, Coptis chinensis French) and* Bayetilla *(Hamelia patens)]* used in the Traditional medicine for an adjuvant effect on the glycemic control of patients with T2DM.(3-7)

Objective: Evaluate efficacy and safety of the phytoformulation Elevaté® as an adjuvant in the treatment of patients with T2DM.

Materials and methods: A 90 days randomized double-blind placebo-controlled trial was conducted. 368 patients with T2DM without or on oral hypoglycemic agents were randomized; 269 in experimental group (1.5g/day of the phytoformulation) and 99 in control group (placebo; 50mg/ Vitamin C per day) In treatment for 90 days. Clinical, somatometric and biochemical parameters through previously and reported. The sample size was calculated with the results of the study on the effects of Moringa Oleifera in patients with type II Diabetes by V. Veeranan Arun Giridhari et al., 2011 with the mean difference formula, 31 patients per group were required to obtain a power of 80% and a CI of 95%.

Results: In the experimental group, cholesterol decreases from 187(160.75-210) mg/dl to 164(119.25-190.50) mg/dl [reduction 25.5 mg/dl] and triglycerides of 174.5 (117-278) mg/ dl to 143.5 (80-208) mg/dl, with $p < 0.001$. HBA1C presented a reduction of 9.09 ± 1.39% to 7.92 ± 1.45% with $p < 0.001$. An experimental subgroup without allopathic treatment was reduced from 8.88 (7.70-9.40) % to 7.70 (6.80-8.60) % with $p < 0.001$.

Conclusion: The results show a potential effective and safe use of Shilajit, Chaga, Moringa, Berberina and Bayetilla in a phytoformulation as co-adjuvant in the glycemic control of patients with T2DM, which has a positive effect on the reduction of risk Cardiometabolic.

Key words: Type 2 diabetes mellitus, glycemic control, HBA1c, phytoformulation Elevate® Body Balance, Herbalism.
Funding and Conflicts of interest This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

References

1. Roden M, Shulman GI. The integrative biology of type 2 diabetes. Nature. 2019 Dec 5;576(7785):51–60.
2. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2022. Diabetes Care. 2022 Jan 1;45(Supplement 1): S17–38.
3. Stohs SJ. Safety and Efficacy of Shilajit (Mumie, Moomiyo). Phytotherapy Research. 2014 Apr;28(4):475–9.
4. Hou Q HWWYHHXXFX. Berberine: A Traditional Natural Product with Novel Biological Activities. Altern Ther Health Med. 2020 Jul; 26:20–7.
5. Noor G, Ahmad MdA, Ahsan F, Mahmood T, Arif M, Khushtar M. A Phytochemical and Ethnopharmacological Recapitulation on Hamelia patens. Drug Res. 2020 May 30;70(05):188–98.
6. Dhakad AK, Ikram M, Sharma S, Khan S, Pandey V V., Singh A. Biological, nutritional, and therapeutic significance of Moringa oleifera Lam. Phytotherapy Research. 2019 Nov 27;33(11):2870–903.
7. Szychowski KA, Skóra B, Pomianek T, Gmiński J. Inonotus obliquus – from folk medicine to clinical use. J Tradit Complement Med. 2021 Jul;11(4):293–302.