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Name of Scholar: Dr. Ghousia Tabassum

Name of Supervisor: Prof. Amir Azam,
Department of Chemistry, JMI, New Delhi

Name of Co-Supervisor: Prof. Dr. M.A. Faroqui,
HOD PG Department of Moalajat,
Govt. Nizamia Tibbi College, Hyderabad.

Name of Department: Department of Biotechnology,

Title of thesis: A RANDOMIZED STANDARD CONTROLLED CLINICAL STUDY TO COMPARE THE SAFETY AND EFFICACY OF A UNANI FORMULATION SAFOOF-E-ZIABETUS DULABI WITH METFORMIN IN DHAYABITUS HARR QISM THANI (TYPE 2 DIABETES MELLITUS)

ABSTRACT

Type 2 Diabetes mellitus (*Dhayabitus Harr Qism Thani*) is a major public health problem affecting millions of people worldwide and it is one of the fastest-growing health challenges of the 21st century. Available synthetic medicines have serious side effects; therefore, medicines of herbal origin have been widely used in the therapeutic management of diabetes mellitus for a long time, and have received renewed attention from scientists globally. The present study envisages Standardization of *Safoof-e-Ziabetus Dulabi* (SZD) as per WHO guidelines with a primary aim to evaluate the comparative safety and efficacy of a Unani Pharmacopoeial compound formulation *Safoof-e-Ziabetus Dulabi* (SZD) with an allopathic drug Metformin in type 2 diabetes mellitus (T2DM) cases. This study was conducted as a randomized, open-label, controlled clinical trial on 120 participants with T2DM at Govt. Nizamia General Hospital during 2019-2021. The Test group (n=60) received the study drug SZD (powder) 6 gm twice daily orally while the Control group (n=60) received the standard drug Metformin 500 mg twice daily orally for 12 weeks. The statistical analysis of data presented was done by using one-way analysis of variance (ANOVA) followed by Dennett's' test and, p value of ≤ 0.05 was considered significant. The results were compared with baseline to different follow-up of two groups of diabetic patients treated with Unani and allopathic drug, namely, SZD and Metformin inferred that the overall effect of the test formulation (SZD) was

found quite effective in the treatment of T2DM and has shown a statistically significant difference on subjective parameters like polydipsia, polyuria polyphagia, nocturia, fatigue and burning sensation of palms and soles, weight loss and giddiness as compared to control drug after 12 weeks of treatment. SZD showed a significant lowering of FBS ($p<0.01$), PPBS ($p<0.05$), and HbA1c ($p<0.001$), almost comparable to that of Metformin in its anti-diabetic activity with marked improvement in the symptoms. The therapeutic response was expressed as mean (±S.D.), in the control group it was found to be 66.74% (±19.22) while test group 60.1% (±19.54) when compared statistically was found to be significant with p-value <0.05. In the control group, out of 60 completed cases, 19 (31.7%) gave a good response, 30 (50%) average response, 9 (15%) fair response and 2 (3.3%) showed a poor response, while in the test group, out of 60 cases, 18 (30%) gave a good response, 24 (40%) average response, 16 (26.7%) fair response and 2 (3.3%) showed poor response. The study's significance on safety parameters was assessed concerning the findings of pre and post-study clinically, hematologically, and biochemically and was found within the normal range. SZD was well tolerated and exhibited no systemic toxicity and was seen to be effective and safe for the management of T2DM by positively altering glucose levels in the blood & lipid profiles and, therefore, recommended for long time use in T2DM cases without any side effects. In conclusion, this study highlights the antidiabetic activity of SZD in reducing FBS, PPBS and HbA1c significantly in diabetic participants at 12 weeks of treatment and thus the claim of Unani medicine regarding the efficacy of SZD in Diabetes Mellitus was validated by the study. Further studies are suggested on a larger sample size, longer study duration and multiple doses.

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