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Controlled clinical study of an Ayurvedic anti-diabetic formulation BGR-34 tablets for its efficacy and safety in patients with diabetes mellitus

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Introduction & Aim: According to International Diabetes Federation, 415 million adults were living with diabetes in 2015 and this number is expected to increase to around 642 million by 2040. The Scientists of India, Council for Scientific & Industrial Research (CSIR) has realized the alarming rise in incidence of diabetes and developed scientifically validated, anti-diabetic ayurvedic drug to prevent and treat Diabetes mellitus type-2. CSIR, has been ranked 12th in the world among the government institutions. The drug has been developed jointly by scientist of National Botanical Research Institute (NBRI) and Central Institute for Medicinal & Aromatic Plants (CIMAP), the Lucknow, India-based research units of CSIR. Scientists of NBRI and CIMAP made an in-depth study on 500 anti-diabetic herbs from ancient literature of Indian System of Medicine Ayurveda (*Caraka Samhita, Sushruta Samhita, Astanga Hridaya and Bhavprakash*) and finally identified the six herbs (*Berberis aristata, Tinospora cordifolia, Pterocarpus marsupium, Gymnema sylvestre, Rubia cordifoila and Trigonella foenumgraecum*). Pre-clinical studies conducted by CSIR on BGR-34 produced encouraging results in diabetes induced experimental subjects (unpublished data CSIR). Encouraged by the preclinical outcome, CSIR moved to investigate the active components from BGR-34 and we moved to test its clinical efficacy, with an aim to ensure the scientific validity, efficacy and safety of BGR-34 on blood glucose regulation with type-2 diabetes mellitus based on clinical studies.

Methodology: A double blind placebo controlled clinical study of BGR-34 in patients with type-2 DM was approved by the independent human ethics committee of Aggarwal Dharmarth Hospital, New Delhi, India.

Findings: BGR-34, showed promising result with respect to glycemic parameters in patient with type-2 diabetes with significant reduction in fasting blood sugar by 34.3%, post prandial blood sugar by 35.5% and glycosylated hemoglobin by 20.31% as compared to placebo group showing reduction by 13.2%, 10.9% and 10.87%, respectively. The trial has also been registered to CTRI, India.

Conclusion & Significance: BGR 34 has been investigated to contain a number of active biomolecule molecules including the compound berberine (*Berberis aristata*), a natural dipeptidyl peptidase IV (DPP-4) inhibitor, that act by increasing endogenous GLP-1 and GIP concentrations. Via this mechanism, insulin secretion is glucose-dependently stimulated and glucagon secretion inhibited.

Biography

Anshu Rathi is working as a Team Lead at Aimil Pharmaceuticals (India)Ltd. Her wide range of publications in various national and international journals.

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