



Clinical Trial Details (PDF Generation Date :- Sat, 24 Feb 2018 00:49:28 GMT)

CTRI Number	CTRI/2016/11/007476 [Registered on: 23/11/2016] - Trial Registered Retrospectively	
Last Modified On	19/01/2017	
Post Graduate Thesis	No	
Type of Trial	Interventional	
Type of Study	Ayurveda	
Study Design	Randomized, Parallel Group Trial	
Public Title of Study	A clinical study of BGR 34, in patients with type 2 diabetes mellitus.	
Scientific Title of Study	Controlled clinical study of an Ayurvedic anti diabetic formulation (BGR-34) for its efficacy and safety in patients with type 2 Diabetes mellitus	
Secondary IDs if Any	Secondary ID	Identifier
	nil	NIL
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Details of Principal Investigator	
	Name	Dr BP Gupta
	Designation	Medical Superintendent
	Affiliation	Aggarwal Dharmath Hospital society registered
	Address	Aggarwal hospital 24/9 Shakti Nagar Affiliation and designation: Medical Superintendent Central DELHI 110007 India
	Phone	9313291669
	Fax	
	Email	adhs_r@yahoo.co.in
Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)	
	Name	Dr BP Gupta
	Designation	Medical Superintendent
	Affiliation	Aggarwal Dharmath Hospital society registered
	Address	Aggarwal hospital 24/9 Shakti Nagar Affiliation and designation: Medical Superintendent Central DELHI 110007 India
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	Fax	
	Email	adhs_r@yahoo.co.in
Source of Monetary or Material Support	Source of Monetary or Material Support	
	> AIMIL PHARMACEUTICALS (INDIA) LIMITED	
Primary Sponsor	Primary Sponsor Details	
	Name	AIMIL PHARMACEUTICALS INDIA LIMITED
	Address	2994/4 STREET NUMBER 17 RANJEET NAGAR NEW DELHI 110008.
	Type of Sponsor	Pharmaceutical industry-Indian
Details of Secondary Sponsor	Name	Address
	NIL	NIL
Countries of Recruitment	List of Countries	
	India	
Sites of Study	Name of Principal Investigator	Name of Site
	Dr BP Gupta	Aggarwal Dharmath Hospital, society registered
		Site Address
		DEPARTMENT OF AYURVEDA DIVISION, AYURVEDIC CLINIC ROOM NUMBER 001 Central DELHI
		Phone/Fax/Email
		9313291669 adhs_r@yahoo.co.in
Details of Ethics Committee	Name of Committee	Approval Status
	INTERNAL ETHICAL COMMITTEE Aggarwal Dharmath Hospital, society registered	Approved
		Date of Approval
		08/09/2014
		Is Independent Ethics Committee?
		No
	INTERNAL ETHICAL COMMITTEE Aggarwal Dharmath Hospital, society registered	Approved
		08/09/2014
		No
Regulatory Clearance Status from DCGI	Status	Date
	Not Applicable	No Date Specified
Health Condition / Problems Studied	Health Type	Condition
	Patients	Type 2 Diabetes Mellitus.
Intervention / Comparator Agent	Type	Name
	Comparator Agent	TRIPHALA as placebo
		Details
		dose: two tablets of 620 mg (containing 250 mg of triphala in under therapeutic concentration) frequency: twice a day before meals. route of administration:oral
	Intervention	BGR-34
		Dose:two tablet of 620 mg frequency:twice a day before meals. route of administration:oral
Inclusion Criteria	Inclusion Criteria	
	Age From	25.00 Year(s)
	Age To	60.00 Year(s)
	Gender	Both



	Details	Patients with type 2 Diabetes mellitus Fasting blood glucose >126 mg/dL Absence of any other significant disease or clinically significant medical history on physical examination during screening in the view of the investigator. Subjects willing to provide written informed consent to participate in the study.
Exclusion Criteria	Exclusion Criteria	
	Details	Patients on Insulin Patients with acute infections or chronic debilitating diseases, tuberculosis, malignancy, HIV infection etc. Any life threatening serious disorder of the liver, kidneys, heart, lungs or other organs Pregnancy and lactation Patients diagnosed with severe end organ damage Unwillingness to give written informed consent for participation in the study.
Method of Generating Random Sequence	Computer generated randomization	
Method of Concealment	Sequentially numbered, sealed, opaque envelopes	
Blinding/Masking	Participant, Investigator, Outcome Assessor and Data-entry Operator Blinded	
Primary Outcome	Outcome	Timepoints
	Assessment has been done on the basis of specially prepared performa for assessing blood sugar fasting and blood sugar post prandial blood sugar on days 0,30,60,90,120 and for HbA1c it is 0 and 120.	Time point of days for blood sugar fasting and blood sugar post prandial blood sugar: 0,30,60,90,120 Time point of days for HbA1c: 0; 120 Time point of days for change in patient reported diabetes symptoms: polyuria, nocturia, polyphagia, polydipsia, pain calf muscle, burning sensations of soles and palm, general fatigue, loss of weight, decreased libido, itching on genital, blurred vision delayed healing of wound and quality of life at: 0,30,60,90,120 days.
Secondary Outcome	Outcome	Timepoints
	Assessment was done on the basis of specially prepared performa for assessing relating parameters indicating safety and additional details.	120 days
Target Sample Size	Total Sample Size=64 Sample Size from India=64	
Phase of Trial	Phase 1/ Phase 2	
Date of First Enrollment (India)	06/10/2014	
Date of First Enrollment (Global)	No Date Specified	
Estimated Duration of Trial	Years=0 Months=4 Days=0	
Recruitment Status of Trial (Global)	Not Applicable	
Recruitment Status of	Closed to Recruitment of Participants	



Trial (India)	
Publication Details	not yet published
Brief Summary	<p>This study is a randomized, double blind, parallel group, comparing the safety and efficacy of BGR-34 daily and <i>Triphala</i> daily for 4 months in 64 patients with diabetes that was conducted in India. The primary outcome of BGR-34 showed very promising results with respect to glycemic parameters in patients with type 2 diabetes mellitus. There was a significant improvement in the feeling of wellbeing due to better control of hyperglycemia. The various mechanism through which the drug showed these results may be probably attributed to i) delays in absorption of glucose from GIT, ii) inhibition of Advanced glycation end products (AGEs) accumulation and iii) enhancing insulin release and improvement in conversion of pro-insulin to insulin. It is further suggested that BGR-34 should be further extensively used as a monotherapy/adjunctive therapy for the regulation/management / control of blood glucose level.</p>