Clinical Trial Details (PDF Generation Date :- Sun, 16 Dec 2018 11:24:30 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)

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Name	Dr BP Gupta
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Address	Aggarwal hospital 24/9 Shakti Nagar Affiliation and designation: Medical Superintendent Central DELHI 110007 India
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Source of Monetary or Material Support

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> 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	Site Address	Phone/Fax/Email
Dr BP Gupta	Aggarwal Dharmath Hospital, society registered	DEPARTMENT Of AYURVEDA DIVISION, AYURVEDIC CLINIC ROOM NUMBER 001 Central DELHI	9313291669 adhs_r@yahoo.co.in

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
INTERNAL ETHICAL COMMITTEE Aggarwal Dharmath Hospital, society registered	Approved	08/09/2014	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	Details
Comparator Agent	TRIPHALA as placebo	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 Date-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 parandial 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 parandial 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, polydispia, 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	**This study is a randomized, double blind, parallel group, comparing the safety and efficacy of BGR-34 daily and *Triphla* 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.**