



Clinical Trial Details (PDF Generation Date :- Thu, 28 Jan 2016 16:36:57 GMT)

CTRI Number	TBA	
Last Modified On		
Post Graduate Thesis		
Type of Trial	Interventional	
Type of Study	Ayurveda	
Study Design	Randomized, Parallel Group, Placebo Controlled Trial	
Public Title of Study	A clinical trial to study the effects of Diabamit tablets on patients with type 2 diabetes mellitus.	
Scientific Title of Study	A randomized Open-Label placebo controlled crossover clinical trial to compare the safety and efficacy of Diabamit Tablets 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	Meenakshi Gupta
	Designation	Doctor (Head)
	Affiliation	Rajkiya Ayurvedic Chikitsalya
	Address	Rajkiya Ayurvedic Chikitsalya, Kela wali Kothi, Abulane, Meerut Meerut UTTAR PRADESH 250001 India
	Phone	9456662949
	Fax	
	Email	NA@NotAvailable.com
Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)	
	Name	Rohtash Mittal
	Designation	Ayurveda Consultant
	Affiliation	MITTAL AYURVED SANSTHAN
	Address	121 B, MANSAROVAR INDUSTRIAL ESTATE EXT., BAGHPAT ROAD, MEERUT 40, Sant Vihar, T.P. Nagar, Meerut Meerut UTTAR PRADESH 250002 India
	Phone	9837015757
	Fax	
	Email	info@mittalayurved.com
Details Contact Person (Public Query)	Details Contact Person (Public Query)	
	Name	PUNEET MITTAL
	Designation	Business Consultant
	Affiliation	MITTAL AYURVED SANSTHAN
	Address	C-10/3, Street-4, Jwala Nagar, T. P. Nagar, Meerut 121 B, MANSAROVAR INDUSTRIAL ESTATE EXT., BAGHPAT ROAD, MEERUT Meerut UTTAR PRADESH 250002 India
	Phone	8937015757



	Fax	
	Email	puneetmittal01@gmail.com
Source of Monetary or Material Support	Source of Monetary or Material Support	
	> Manufacturing company- Mittal Ayurved Sansthan, Meerut[Research Budgeting department]	
	> Rajkiya Ayurvedic Chikitsalya- A 25 bed Ayurvedic Hospital in Meerut	
Primary Sponsor	Primary Sponsor Details	
	Name	Mittal Ayurved Sansthan
	Address	121-B, Mansarovar Industrial Estate Ext., Inside Vishvakarma Industrial Estate Baghpat Road, Panchli, Meerut-250002 Uttar Pradesh, INDIA
	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 Meenakshi Gupta	Rajkiya Ayurvedic Chikitsalya
		Site Address
		161, Abulane Meerut [Kele Wali Gali] Meerut UTTAR PRADESH
		Phone/Fax/Email
		9456662949 NA@NotAvailable.com
Details of Ethics Committee	Name of Committee	Approval Status
	AYUSH	Approved
		Date of Approval
		20/10/2015
		Is Independent Ethics Committee?
		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
	Intervention	Diabamit Tablet
		Details
		A formulation by Mittal Ayurved Sansthan
	Comparator Agent	Dosage
		700 mg x (3/4) tabs BD for 2 months
Inclusion Criteria	Inclusion Criteria	
	Age From	29.00 Year(s)
	Age To	84.00 Year(s)
	Gender	Both
	Details	fasting glucose levels of greater than 126 mg/dl or random blood glucose greater than 200 mg/dl, HbA1c greater than or equal to 6.5%, 2 h blood glucose on 75 g oral glucose tolerance test (OGTT) greater than or equal to 200 mg/dl, or current treatment with hypoglycemic therapy).
Exclusion Criteria	Exclusion Criteria	
	Details	A history of coronary heart disease or stroke, serum creatinine >1.5 mg/dl, albuminuria >40 ?g/min, and use of lipid-lowering drugs, aspirin, or other antihypertensive agents.
Method of Generating Random Sequence	Stratified randomization	
Method of	Pharmacy-controlled Randomization	



Concealment		
Blinding/Masking	Open Label	
Primary Outcome	Outcome	Timepoints
	Blood Glucose level Data Measured for Most patients dropeed to less than 120 mg/dL[Fasting], and 150 mg/dL[Regular]	Blood Glucose level Data Measured for Most patients dropeed to less than 120 mg/dL[Fasting], and 150 mg/dL[Regular]
Secondary Outcome	Outcome	Timepoints
	Better Sleep observed in All Patients. Lower joint pain issues in 2 patients.	NA
Target Sample Size	Total Sample Size=100 Sample Size from India=100	
Phase of Trial	Phase 2	
Date of First Enrollment (India)	20/10/2015	
Date of First Enrollment (Global)	20/10/2015	
Estimated Duration of Trial	Years=0 Months=2 Days=0	
Recruitment Status of Trial (Global)	Completed	
Recruitment Status of Trial (India)	Completed	
Publication Details	NA	
Brief Summary	This study is a randomized, Open label, Single center trail comparing the efficacy of Diabamit Tabs daily for 2 months on 100 patients with diabetes that will be conducted in one center in India. The primary outcome- Blood Glucose level Data Measured for Most patients dropped to less than 120 mg/dL[Fasting], and 150 mg/dL[Regular]	