Clinical Trial Details (PDF Generation Date :- Fri, 27 Jan 2023 19:15:04 GMT)

CTRI Number	CTRI/2010/091/001507 [Registered on: 15/10/2010] -
Last Modified On	26/02/2013
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug
Study Design	Randomized, Parallel Group, Active Controlled Trial
Public Title of Study	A clinical trial to evaluate efficacy and safety of three drug combination (telmisartan + hydrochlorthiazide + amlodipine) in the treatment of patients suffering from essential hypertension
Scientific Title of Study	COmparative study evaluating Normalisation of blood pressure with TRiple pill as Outcome against teLmisartan/hydrochlorothiazide in Hypertension (CONTROL-Hypertension Study): A randomized, controlled, double-blind, double-dummy multicenter study to evaluate the efficacy and safety of the combination of Telmisartan/HCTZ/Amlodipine compared to Telmisartan/HCTZ in patients with Essential Hypertension.

Secondary IDs if Any

Secondary ID	Identifier
CONTROL-H/GMA/2010	Protocol Number

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr Shilpi Dhawan
Designation	
Affiliation	
Address	6-3-865, 3rdfloor , Madhupala Towers , Global Medical Affairs Dr Reddys Laboratories Ltd, Ameerpet Hyderabad ANDHRA PRADESH 500016 India
Phone	040-30783221
Fax	040-66511536
Email	shilpid@drreddys.com

Details Contact Person (Scientific Query)

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Name	Dr Shilpi Dhawan
Designation	
Affiliation	
Address	6-3-865, 3rdfloor , Madhupala Towers , Global Medical Affairs Dr Reddys Laboratories Ltd, Ameerpet Hyderabad ANDHRA PRADESH 500016 India
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	500016 India
Phone	040-30783221
Fax	040-66511536
Email	shilpid@drreddys.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> Dr Reddys Laboratories Ltd , 8-1027, Road No.:3 Banjara Hills, Hyderabad , INDIA

Primary Sponsor

Primary Sponsor Details	
Name	Dr Reddys Laboratories Ltd
Address	8-2-337, Road No:3 , Banjara Hills , Hyderabad-500034
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
NIL	

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr T.V.Devarajan	Apollo Hospital	First Med,P.H.Road-600010 Chennai TAMIL NADU	044-2821111 044-28237470 FIRSTMEDHOAPITAL@APOLLOHOSPITALS.COM
Dr. Abraham Oomman	Apollo Hospitals	# 645 & 646, TH Road, Tondiarpet,-600081 Not Applicable N/A	9940754427 aherfchennai@gmail.com
Dr.Satish Kinagi	Basaveshwar Hospital	Sedam Road,-585105 Gulbarga KARNATAKA	9448149091 drsatish_kinagi@hotmail.com
Dr Siddharth N.Shah	Bhatia Hospital	Bhatia Hospital , ,-40008 Mumbai MAHARASHTRA	9819888500 apitxtbk@vsnl.net
Dr. K A Sambasivam	GKNM Hospital (G.Kuppuswamy Naidu Memorial Hospital)	Dept. of Cardiology,P.B.No. 6327 , Nethaji Road -641037 Coimbatore TAMIL NADU	9842221796 drsambasivam@yahoo.com
Dr.PLN Kapardhi	Global Hospitals	Consultant Cardiologist,Global Hospitals6-1-1070/1 to 4Lakdi-Ka-Pool, -500004 Hyderabad ANDHRA PRADESH	9848047521 yamsani.ashwin@gmail.com
Dr. Jacob Jayan. B	Govt. Medical College	Lecturer in Medicine,Department of General MedicineGovt. Medical CollegeVandanam-688005 Not Applicable	9447075720 drjacob.jayan@gmail.com

		N/A	
Dr Shiva Shankar Polavarapu	Hyderabad Diabetic Centre	near Image Hospital ,Ameerpet-500023 Hyderabad ANDHRA PRADESH	040-23752828 hyddiabetes@gmail.com
Dr B.L.N.Prasad	King George Hospital	Department of Medicine , Unit VI (6), King George Hospital ,Andhra Medical College,-530002 Visakhapatnam ANDHRA PRADESH	9848211931 drblnprasad@yahoo.com
Dr. Satish Rao B	KMC Hospital	Associate professor ,Department of medicine-575001 Bangalore KARNATAKA	9845348475 drsatishrao1971@yahoo.com
Dr K Chockalingam	Kovai Medical Center Kovai Medical Center and Hospital Limited	P.B.No. 3209 , Avanashi Road ,Dept of cardiology-641 014 Coimbatore TAMIL NADU	9842221796 04224323124 kclingam@gmail.com
Dr Sindhu Joshi	Mahavir Hospital & Research Centre, hyderabad	10-1-1A C Guards , Masab Tank, ,-500004 Hyderabad ANDHRA PRADESH	9391099991 dr_sindhu@yahoo.com
Dr Naveen Chandra Reddy	Mediciti Hospital	5-9-22, Secretrait Road ,-500023 Hyderabad ANDHRA PRADESH	9848045814 prodduturnaveen@yahoo.co.in
Dr Sampath Kumar	Osmania General Hospital	Department of Cardiology , Osmania General Hospital , Afzalgunj ,-500012 Hyderabad ANDHRA PRADESH	9848033468 drsampath53@yahoo.com
Dr Jagdish S.Hiremath	Poona Hospital & Research Centre	27, Sadashiv Pet ,-411030 Pune MAHARASHTRA	9890903256 drjagdeshhiremath@gmail.com
Dr Manju Bhargavi	Radix Diabetes Centre	#29-9-60/1 , GovindarajuluNaidu Street ,Surayaraopet, ,-520002 Not Applicable N/A	9246474723 drmanjub@gmail.com
Dr Parth N Patel	St Theresa General Hospital	erragadda,-500019 Hyderabad ANDHRA PRADESH	04023814556 parthnp@yahoo.com
Dr. KP Paulose	SUT Hospital	Chief Physician & Diabetologis,Pattom,-695004 Not Applicable N/A	9447144434 kpp_sut@ymail.com
Dr. Ganesh Mathan	Yashoda Hospital	Somajiguda,-500019 Hyderabad ANDHRA PRADESH	9866608856 mganesh7@yahoo.co.uk

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Basaveshwar Hospital ,Institutional Ethics Committee	Approved	No Date Specified	Not Available
Bhatia Hospital, Institutional Ethics Committee	Approved	No Date Specified	Not Available
Institutional Ethics Committee , Apollo Hospitals	Approved	No Date Specified	Not Available
Institutional Ethics Committee, Govt. Medical College	Submittted/Under Review	No Date Specified	No
Institutional Ethics Committee, Kovai Medical Centre	Approved	No Date Specified	Not Available
Institutional Ethics Committee, SUT Hospital	Approved	No Date Specified	Not Available
Institutional Ethics Committee,,Global Hospitals	Submittted/Under Review	No Date Specified	Not Available
Institutional Ethics CommitteeGKNM Hospital	Approved	No Date Specified	Not Available
Institutional Ethics CommitteeMediciti Hospital	Approved	No Date Specified	Not Available
KGH Vizag,Institutional Ethics Committee,	Approved	No Date Specified	Not Available
KMC Hospital,Institutional Ethics Committee	Approved	No Date Specified	Not Available
Mahavir Hospital ,Institutional Ethics Committee	Approved	No Date Specified	Not Available
Osmania Hospital ,Institutional Ethics Committee	Submittted/Under Review	No Date Specified	Not Available
Poona Hospital ,Institutional Ethics Committee	Submittted/Under Review	No Date Specified	Not Available
Radix Diabetes Hospital,Institutional Ethics Committee	Approved	No Date Specified	Not Available
Yashoda Hospital,Institutional Ethics Committee	Submittted/Under Review	No Date Specified	Not Available

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	06/10/2010

Health Condition / Problems Studied

Health Type	Condition
Patients	Essential Hypertension

Intervention /

Type	Name	Details

Comparator Agent

Intervention	Telmisartan + hydrochlorthiazide +amlodipine	Once daily , 8 weeks
Comparator Agent	telmisartan + hydrochlorthiazide	Once daily , 8 weeks

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	65.00 Year(s)
Gender	Both
Details	1. Patients of both sexes of age ≥ 18 years and ≤ 65 years 2. Patients with uncontrolled hypertension (SBP ≥ 140 mmHg and ≤ 179 mmHg; DBP ≥ 90 mmHg and ≤ 109 mmHg) when treated with full dose of monotherapy (Appendix III) or any of the combinations at the specified doses equipotent to or doses less potent than telmisartan 40 mg + Hydrochlorothiazide 12.5 mg given together (Appendix IV) 3. Non-diabetic patients or Type II diabetic patients with stabilized glycaemic control 4. Patients without CAD or patients with stable angina

Exclusion Criteria

Exclusion Criteria	
Details	1. Patients with Stage 2 hypertension with SBP ≥ 180 mmHg and DBP ≥ 110 mmHg 2. Patients with uncontrolled hypertension (SBP ≥ 140 mmHg and DBP ≥ 90 mmHg) when treated with doses of monotherapy, less than that mentioned in Appendix III 3. Patients with uncontrolled hypertension (SBP ≥ 140 mmHg and DBP ≥ 90 mmHg) when treated with any of the combinations at doses more potent than Telmisartan 40 mg + Hydrochlorothiazide 12.5 mg given together (doses higher than those given in appendix IV) 4. Patients with uncontrolled hypertension with combination containing beta blockers or three or more antihypertensive agents 5. Patients with history of unstable angina, myocardial infarction, Stroke, TIA or heart failure 6. Patients with history of moderate or malignant retinopathy, history of hypertensive encephalopathy, arrhythmias, sinus tachycardia or electrolyte imbalance 7. Patients with 2nd or 3rd degree heart block, clinically significant valvular heart disease 8. Patients with uncontrolled diabetes (HbA1c ≥ 9%) 9. Serum creatinine > 1.5 times the upper limit of normal (ULN) 10. Patients with history of hypersensitivity to any of the components of triple pill or sulphonamides 11. Patients with chronic inflammatory conditions, gouty arthritis or other conditions that require the continuous use of NSAIDs 12. Systemic Lupus Erythematosus 13. Acute medical conditions/ surgeries/ alcoholism 14. Medical/ psychiatric conditions likely to hinder trial process 15. Lactating and pregnant women. 16. Women of reproductive age, not practicing reliable contraception. 17. Hepatic dysfunction (AST/ALT/AlkPO4 > 3 times upper limit of normal/ Bilirubin > 1.5 times upper limit of normal (ULN)/ Known hepatic cirrhosis) or existing biliary obstruction

Method of Generating Random Sequence	Stratified block randomization
Method of Concealment	Sequentially numbered, sealed, opaque envelopes
Blinding/Masking	Participant, Investigator, Outcome Assessor and Date-entry Operator Blinded

Primary Outcome

Outcome	Timepoints
Normalization of blood pressure (SBP 139 & DBP 89 mm Hg in non-diabetics and SBP 129 & DBP 79 mm Hg in diabetics) at the end of 8 weeks treatment period.	Baseline and end of treatment (8 weeks)

Secondary Outcome	**Outcome**	**Timepoints**
	weeks. ? Change from baseline systolic blood pressure at the end of 8 weeks. ? Systolic blood pressure normalization (SBP ? 139 mmHg in non-diabetics and SBP ? 129 mm Hg in diabetics) or diastolic blood pressure normalization (DBP ? 89 mmHg in non-diabetics and DBP ? 79 mm Hg in diabetics) at the end of 8 weeks. ? Difference in BP responder rates at the end of 8 weeks as assessed by:	Baseline and end of treatment (8 weeks)

Target Sample Size	**Total Sample Size=**512 **Sample Size from India=**512 **Final Enrollment numbers achieved (Total)=** **Final Enrollment numbers achieved (India)=**
Phase of Trial	Phase 3
Date of First Enrollment (India)	15/11/2010
Date of First Enrollment (Global)	15/11/2010
Estimated Duration of Trial	**Years=**0 **Months=**8 **Days=**0
Recruitment Status of Trial (Global)	Completed
Recruitment Status of Trial (India)	Completed
Publication Details	NIL
Brief Summary	This is a phase III randomized , double - blind , double dummy multicenteric trial to evaluate the efficacy and safety of triple drug combination of temisartan / hydrochlorthiazide / amlodipine compared to telmisartan / hydrochlorthiazide in the treatment of essential hypertension