



Clinical Trial Details (PDF Generation Date :- Thu, 23 May 2013 04:40:27 GMT)

<b>CTRI Number</b>	CTRI/2011/09/002027 [Registered on: 29/09/2011] - <b>Trial Registered Retrospectively</b>	
<b>Last Modified On</b>	20/09/2011	
<b>Post Graduate Thesis</b>	No	
<b>Type of Trial</b>	Observational	
<b>Type of Study</b>	Double Blind Crossover Study	
<b>Study Design</b>	Randomized, Crossover Trial	
<b>Public Title of Study</b>	"MAX ENVIRONICS 001 :A double blind crossover study to evaluate the efficacy of Environics Anti radiation chips in a healthcare environment."	
<b>Scientific Title of Study</b>	MAX ENVIRONICS 001: " A double blind crossover study to evaluate the efficacy of Environics Anti radiation chips in a healthcare environment"	
<b>Secondary IDs if Any</b>	<b>Secondary ID</b>	<b>Identifier</b>
	NIL	NIL
<b>Details of Principal Investigator or overall Trial Coordinator (multi-center study)</b>	<b>Details of Principal Investigator</b>	
	<b>Name</b>	Dr Vanita Mittal
	<b>Designation</b>	Senior Manager Training & ITC Coordinator
	<b>Affiliation</b>	Max Hospital
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<b>Details Contact Person (Scientific Query)</b>	<b>Details Contact Person (Scientific Query)</b>	
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<b>Details Contact Person (Public Query)</b>	<b>Details Contact Person (Public Query)</b>	
	<b>Name</b>	Sunita Rana
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<b>Source of Monetary or Material Support</b>	<b>Source of Monetary or Material Support</b>			
	> All the expenses have been born by the sponsor			
<b>Primary Sponsor</b>	<b>Primary Sponsor Details</b>			
<b>Name</b>	Syenergy Environics Ltd			
<b>Address</b>	Syenergy Environics Ltd. 206, Palza 1 , South Extension Part 2, Masjid Moth New Delhi 110049			
<b>Type of Sponsor</b>	Other [Public Limited Company]			
<b>Details of Secondary Sponsor</b>	<b>Name</b>	<b>Address</b>		
	NIL	NIL		
<b>Countries of Recruitment</b>	<b>List of Countries</b>			
	India			
<b>Sites of Study</b>	<b>Name of Principal Investigator</b>	<b>Name of Site</b>	<b>Site Address</b>	<b>Phone/Fax/Email</b>
	Dr Vanita Mittal	Max Hospital , saket	Max Super Speciality Hospital 1, Press Enclave Road, Saket New Delhi 110017 New Delhi DELHI	9810595053 vanita.mittal@maxhealthcare.com
<b>Details of Ethics Committee</b>	<b>Name of Committee</b>	<b>Approval Status</b>	<b>Date of Approval</b>	<b>Is Independent Ethics Committee?</b>
	The Max Healthcare Ethics Committee	Approved	27/05/2011	Yes
<b>Regulatory Clearance Status from DCGI</b>	<b>Status</b>		<b>Date</b>	
	Not Applicable		No Date Specified	
<b>Health Condition / Problems Studied</b>	<b>Health Type</b>		<b>Condition</b>	
	Healthy Human Volunteers		Subjects whose pulse rate increased above 82 due to exposure of Electromagnetic radiations.	
<b>Intervention / Comparator Agent</b>	<b>Type</b>	<b>Name</b>	<b>Details</b>	
<b>Inclusion Criteria</b>	<b>Inclusion Criteria</b>			
	<b>Age From</b>	20.00 Year(s)		
	<b>Age To</b>	60.00 Year(s)		
	<b>Gender</b>	Both		
	<b>Details</b>	Healthy Human Subjects having pulse rate above 82 and using eiither mobile phone , computer or both		
<b>Exclusion Criteria</b>	<b>Exclusion Criteria</b>			
	<b>Details</b>	unhealthy subjects,subjects having pulse rate below 82 and those who neither use mobile phone nor computeres		
<b>Method of Generating Random Sequence</b>	Not Applicable			
<b>Method of Concealment</b>	Not Applicable			
<b>Blinding/Masking</b>	Not Applicable			
<b>Primary Outcome</b>	<b>Outcome</b>		<b>Timepoints</b>	
	Reduction in the pulse rate of those having		Testing the efficacy of Enviro Chip on pulse rate	



	increased pulse rate of 82 or above after using Enviro chip on their mobiles and computers.	of those having pulse rate above 82 due to exposure of ElectroMagnetic radiations
<b>Secondary Outcome</b>	<b>Outcome</b>	<b>Timepoints</b>
	Not applicable	Not applicable
<b>Target Sample Size</b>	<b>Total Sample Size=150</b> <b>Sample Size from India=150</b>	
<b>Phase of Trial</b>	N/A	
<b>Date of First Enrollment (India)</b>	30/06/2011	
<b>Date of First Enrollment (Global)</b>	No Date Specified	
<b>Estimated Duration of Trial</b>	<b>Years=0</b> <b>Months=2</b> <b>Days=0</b>	
<b>Recruitment Status of Trial (Global)</b>	Not Applicable	
<b>Recruitment Status of Trial (India)</b>	Completed	
<b>Publication Details</b>	Will be done after approval by MHEC	
<b>Brief Summary</b>	<p>The hypothesis of the sponsor is based on the finding that people subjected to excessive microwave Radiation tend to get stressed and suffer loss of immunity. This is found most commonly to occur due to excessive use of Cell Phones and Computers since they are in close proximity to the body. This has been found to increase their pulse rate. It has been found that those having a lower immunity show a higher increase in the pulse rate and those having high immunity show no or marginal increase.</p> <p>For the study, we have agreed to study the effect of the actual and dummy chip on the pulse rate of people subjected excessively to microwave radiations from mobile phones and computers with a pulse rate after usage of more than 82 per minute, which can be considered high. a substantial reduction between 4 to 5% can be expected on a statistically significant sample size.</p>	