



Clinical Trial Details (PDF Generation Date :- Tue, 05 Oct 2021 05:15:57 GMT)

<b>CTRI Number</b>	CTRI/2021/10/037082 [Registered on: 05/10/2021] - <b>Trial Registered Prospectively</b>	
<b>Last Modified On</b>	04/10/2021	
<b>Post Graduate Thesis</b>	No	
<b>Type of Trial</b>	Interventional	
<b>Type of Study</b>	Ayurveda	
<b>Study Design</b>	Single Arm Trial	
<b>Public Title of Study</b>	To investigate the efficacy of AyuBreth - a mouth spray	
<b>Scientific Title of Study</b>	Bronchodilator Effect of AyuBreth in Respiratory Tract Disorders	
<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 Prerak Shah
	<b>Designation</b>	Head Ayulink Ayurveda
	<b>Affiliation</b>	Ayulink Ayurveda
	<b>Address</b>	Ayulink Ayurveda Silver spring B/h Xaviers ladies hostel Navrangpura Ahmedabad Ahmadabad GUJARAT 3800009 India
	<b>Phone</b>	9426616025
	<b>Fax</b>	
	<b>Email</b>	info@ayulink.com
<b>Details Contact Person (Scientific Query)</b>	<b>Details Contact Person (Scientific Query)</b>	
	<b>Name</b>	Dr Prerak Shah
	<b>Designation</b>	Head Ayulink Ayurveda
	<b>Affiliation</b>	Ayulink Ayurveda
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	<b>Phone</b>	9426616025



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	<b>Email</b>	info@ayulink.com		
<b>Source of Monetary or Material Support</b>	<b>Source of Monetary or Material Support</b>			
	> Ayulink Ayurveda, Ayulink Ayurveda Silver spring B/h Xaviers ladies hostel Navrangpura Ahmedabad			
<b>Primary Sponsor</b>	<b>Primary Sponsor Details</b>			
	<b>Name</b>	Dr Prerak Shah		
	<b>Address</b>	Ayulink Ayurveda Silver spring, B/h Xaviers ladies hostel Navrangpura, Ahmedabad		
	<b>Type of Sponsor</b>	Other [SELF]		
<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 Prerak Shah	Dr. Jivraj Mehta Smarak Health Foundation	Dr. Jivraj Mehta Smarak Health Foundation Department of Ayurveda Dr. Jivraj Mehta Marg, Paldi, Ahmedabad Gujarat 380007 Ahmadabad GUJARAT	9426616025 info@ayulink.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>
	Dr. Jivraj Mehta Smarak Health Foundation	Approved	03/09/2021	No
<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>		
	Patients	Acute bronchitis, unspecified		
<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>	16.00 Year(s)		
	<b>Age To</b>	99.00 Year(s)		
	<b>Gender</b>	Both		
	<b>Details</b>	Patients with any respiratory tract complains Age: Minimum age of 16 years Males and females Able to understand requirements of the study and risks involved Able to sign a consent form. Existing diagnosis of Asthma, Bronchitis or any respiratory tract diseases by a qualified medical practitioner or PI		
<b>Exclusion Criteria</b>	<b>Exclusion Criteria</b>			
	<b>Details</b>	Pregnant patient Patient with life threatening disorders or conditions Is currently participating in any other clinical trial		



<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>
	Effectiveness of AyuBreth by evaluating the comfort in breathlessness and other respiratory tract disorders Evaluate immediate bronchodilation effect of AyuBreth	6 days
<b>Secondary Outcome</b>	<b>Outcome</b>	<b>Timepoints</b>
	Evaluate immediate bronchodilation effect of AyuBreth	6 days
<b>Target Sample Size</b>	<b>Total Sample Size=100</b> <b>Sample Size from India=100</b> <b>Final Enrollment numbers achieved (Total)=Applicable only for Completed/Terminated trials</b> <b>Final Enrollment numbers achieved (India)=Applicable only for Completed/Terminated trials</b>	
<b>Phase of Trial</b>	N/A	
<b>Date of First Enrollment (India)</b>	06/10/2021	
<b>Date of First Enrollment (Global)</b>	No Date Specified	
<b>Estimated Duration of Trial</b>	<b>Years=0</b> <b>Months=6</b> <b>Days=0</b>	
<b>Recruitment Status of Trial (Global)</b>	Not Applicable	
<b>Recruitment Status of Trial (India)</b>	Not Yet Recruiting	
<b>Publication Details</b>		
<b>Brief Summary</b>	<p>AyuBreth is an introduction of "mouth spray" concept in the field of Ayurveda medicine. It is a different presentation form of medicine. It uses different pathway of management approach in the field of Ayurveda, (which was never thought by anybody). Herbal drug delivery bypassing Liver Metabolism and entering direct into lungs is completely new concept in Ayurveda Pharmacy (Process Innovation).</p> <p>This product makes Ayurveda more acceptable in large population by providing safer and faster relief in respiratory tract diseases.</p>	