Clinical Trial Details (PDF Generation Date :- Sat, 25 Mar 2023 05:21:07 GMT)

CTRI Number	CTRI/2018/08/015237 [Registered on: 08/08/2018] - **Trial Registered Prospectively**
Last Modified On	19/11/2019
Post Graduate Thesis	No
Type of Trial	Observational
Type of Study	Device validation study
Study Design	Other
Public Title of Study	A clinical validation of respiratory medical device and its correlation with clinical tests and diagnosis
Scientific Title of Study	Respiratory sound analysis and correlation with clinical tests and clinical diagnosis

Secondary IDs if Any

Secondary ID	Identifier
SALCIT/2018/001	Protocol Number

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

Details of Principal Investigator	
Name	Dr Sai Praveen Haranath
Designation	Consultant Intensivist and Consultant Pulmonologist
Affiliation	Apollo Hospitals
Address	Apollo Hospitals Jubilee Hills Hyderabad Hyderabad ANDHRA PRADESH 500096 India
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Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Narayana Rao Sripada
Designation	Chief Executive Officer
Affiliation	SALCIT TECHNOLOGIES PRIVATE LIMITED
Address	Flat No 2408 Sai Dream Castle Apartment Nizampet Road KUKATPALLY Hyderabad Telangana Hyderabad ANDHRA PRADESH 500090 India
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Source of Monetary or Material Support

Source of Monetary or Material Support
> SALCIT TECHNOLOGIES PRIVATE LIMITED, Flat No 2408, Sai Dream Castle Apartment, Nizampet Road,KUKATPALLY, Hyderabad, Telangana, 500090

Primary Sponsor

Primary Sponsor Details	
Name	SALCIT TECHNOLOGIES PRIVATE LIMITED
Address	Flat No 2408, Sai Dream Castle Apartment, Nizampet Road,KUKATPALLY, Hyderabad, Telangana, 500090
Type of Sponsor	Other [IT COMPANY WHICH IS INTO HEALTH CARE SERVICES]

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 Sai Praveen Haranath	Apollo Hospital	Room No 9054, Pulmonology Department, Basement 01, Main block, Apollo Hospitals, Jubilee Hills Hyderabad ANDHRA PRADESH	919866415551 indialungdoc@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethics Committee-Clinical Studies (IEC-CS)	Approved	24/07/2018	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Other specified respiratory disorders

Intervention / Comparator Agent

Type	Name	Details

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	99.00 Year(s)
Gender	Both
Details	1. Written signed and dated informed consent (patient or LAR) 2. Either gender with age 18 years and above. 3. Subjects suffering with CRD's, Pulmonary Tuberculosis, CHF and Pulmonary Fibrosis.

Exclusion Criteria

Exclusion Criteria	
Details	1. Subjects who require ventilation, flow of oxygen must be excluded from the study.

Method of Generating Random Sequence	Not Applicable
Method of Concealment	Not Applicable
Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
1. Test the hypothesis that the sound characteristics differ for various CRDs. Sound characteristics can be used in determining severity of inflammation. 2.Test the hypothesis that sound characteristics have correlation with clinical test like spirometry and associated parameters, bed side lung function tests and clinical diagnosis.	For each subject minimum of 5 records are required for in-patients. 2 records on the first and second day of admission. 2 records during course of treatment (after first or second day and prior to discharge) 1 record during discharge (or during stable state) For each outpatient a minimum of 2 records will be attempted.

Secondary Outcome

Outcome	Timepoints
Test the hypothesis that sound characteristics have correlation with clinical test like spirometry and associated parameters, bed side lung function tests and clinical diagnosis.	For each subject minimum of 5 records are required for in-patients. 2 records on the first and second day of admission. 2 records during course of treatment (after first or second day and prior to discharge) 1 record during discharge (or during stable state) For each outpatient a minimum of 2 records will be attempted.

Target Sample Size	**Total Sample Size=**100 **Sample Size from India=**100 **Final Enrollment numbers achieved (Total)=**110 **Final Enrollment numbers achieved (India)=**110
Phase of Trial	N/A
Date of First Enrollment (India)	03/09/2018
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**6 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	None Yet
Brief Summary	This is a validation study to analyze the data delivered by the study device and correlate with clinical tests and diagnosis. This study will analyze the respiratory sounds characteristics of the patients suffering from various chronic respiratory diseases, pulmonary tuberculosis, and congestive heart failure.