Clinical Trial Details (PDF Generation Date :- Fri, 16 Apr 2021 20:13:47 GMT)

CTRI Number	CTRI/2020/08/027477 [Registered on: 31/08/2020] - **Trial Registered Prospectively**
Last Modified On	06/12/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug Ayurveda
Study Design	Single Arm Trial
Public Title of Study	Evaluation of safety and efficacy of T-AYU-HM Premium and Onion steam vaporization/nebulization in Covid-19 patients.
Scientific Title of Study	Evaluation of safety and efficacy of T-AYU-HM Premium and Onion Steam vaporisation/nebulization in Covid-19 patients (mild to moderate)

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	Dr Atul M Desai
Designation	Proprietor
Affiliation	Dhanvantari Clinic, Ayurveda health care and research center
Address	Room no: 301, Ayurveda, Shreeji Desai market, Sardar Chowk Vyara-394650, Gujarat. India Surat GUJARAT 394650 India
Phone	9879031621
Fax	
Email	dratuldesai@rediffmail.com

Details Contact Person (Scientific Query)

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Name	Dr Atul M Desai
Designation	Proprietor
Affiliation	Dhanvantari Clinic, Ayurveda health care and research center
Address	Room no: 301, Ayurveda, Shreeji Desai market, Sardar Chowk Vyara-394650, Gujarat. India Surat GUJARAT 394650 India
Phone	9879031621
Fax	
Email	dratuldesai@rediffmail.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr Hemshree Desai
Designation	MD
Affiliation	ATBU Harita Pharmaceuticals PVT LTD
Address	ATBU Harita Pharmaceuticals Pvt ltd. Room No:110, Shreeji Desai Market Sardar Chowk Vyara Surat GUJARAT 394650 India

Phone	9558054500
Fax	
Email	hemshree94@gmail.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> ATBU Harita Pharmaceuticals Pvt ltd. 110, Shreeji Desai Market, Sardar Chowk Vyara - 394650, Gujarat, India
> Dhanvantari Clinic, Ayurveda Health Care and Research Center 301, Shreeji Desai market, Sardar Chowk Vyara-394650, Gujarat. India

Primary Sponsor

Primary Sponsor Details	
Name	Dhanvantari Clinic Ayurveda Health Care and Research Center
Address	Shreeji Desai Market, Vyara-394650, Gujarat. India
Type of Sponsor	Private hospital/clinic

Details of Secondary Sponsor

Name	Address
ATBU Harita Pharmaceuticals Pvt ltd	Vyara,Gujarat,India. Email: atbuharita@gmail.com

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Atul Desai	Dhanvantari Clinic, Ayurveda Health Care and Research Center	Shreeji Desai Market, Vyara-394650, Gujarat. India Surat GUJARAT	9879031621 dratuldesai@rediffmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
DivyajyotiTrust	Approved	19/08/2020	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Coronavirus as the cause of diseases classified elsewhere

Intervention / Comparator Agent

Type	Name	Details
Intervention	Tablet T-AYU-HM Premium	600mg orally BD for 21 days.
Intervention	Onion steam vaporization/nebulisation	Nasally OD for 21 days
Comparator Agent	NA	NA

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	80.00 Year(s)
Gender	Both
Details	1. Age 18-80 years, 2. Both male and female 3. Mild to Moderate cases under home quarantine. 4. Willing to perform onion vaporization/nebulization? once a day 5. Patients able to consume oral formulations. 6. Willing to provide informed consent.

Exclusion Criteria

Exclusion Criteria	
Details	1. Require mechanical ventilation 2. Unable to perform onion vaporization/nebulisation once a day.

	3. Having serious stages illness 4. Pregnant/lactating women 5. Children below 18 years age

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

Primary Outcome

Outcome	Timepoints
1. Total number of participants with improvement in clinical symptoms – fever, Cough, Fatigue, Shortness of breath, Expectoration, Myalgia, Rhinorrhoea, Sore throat, Diarrhoea, Loss of smell (anosmia), Loss of taste (ageusia). 2. Total number of participants with resolution of clinical symptoms fever, Cough, Fatigue, Shortness of breath, Expectoration, Myalgia, Rhinorrhoea, Sore throat, Diarrhoea, Loss of smell (anosmia), Loss of taste (ageusia).	21 days

Secondary Outcome

Outcome	Timepoints
1. Oxygen requirement of patients 2. Improvement in oxygen saturation 3. Improvement in respiratory rate 4. Improvement in haematological parameters 5. Improvement in the level of other inflammatory markers CRP, ESR, LDH	Baseline 5th day 21th day

Target Sample Size	**Total Sample Size=**30 **Sample Size from India=**30 **Final Enrollment numbers achieved (Total)=**30 **Final Enrollment numbers achieved (India)=**30
Phase of Trial	Phase 2
Date of First Enrollment (India)	03/09/2020
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**0 **Days=**21
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	NIL
Brief Summary	This study is a single arm, open label trial to evaluate the safety and efficacy of T-AYU-HM Premium 600 mg BD for 21 days and Onion steam

vaporization/nebulization OD for 21 days in patients with COVID 19 that will be conducted at Dhanvantari Clinic, Ayurveda Health Care and Research Centre in India. The primary outcome measures will be improvement in clinical symptoms - cough, fever with or without chills, difficulty in breathing, headache, sore throat and resolution of clinical symptoms by the end of the treatment. Secondary outcomes will be reduction in oxygen requirement of patients, improvement in oxygen saturation, improvement in respiratory rate, improvement in hematological parameters, improvement in the level of inflammatory markers.