Clinical Trial Details (PDF Generation Date :- Sun, 26 Mar 2023 13:15:56 GMT)

CTRI Number	CTRI/2020/06/025998 [Registered on: 20/06/2020] - **Trial Registered Prospectively**
Last Modified On	18/06/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug Ayurveda
Study Design	Randomized, Parallel Group, Placebo Controlled Trial
Public Title of Study	Efficacy of An Ayurvedic Preparation Raj Nirwan Bati (RNB) on symptomatic COVID-19 Patients
Scientific Title of Study	To Determine the Efficacy of An Ayurvedic Preparation Raj Nirwan Bati (RNB) on symptomatic COVID-19 Patients: A Double-Blind Randomized Controlled Trial

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

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

Details of Principal Investigator	
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Source of Monetary or Material Support

Source of Monetary or Material Support
> Uttar Pradesh University of Medical Sciences, Saifai, Etawah, UP

Primary Sponsor

Primary Sponsor Details	
Name	Uttar Pradesh University of Medical Sciences
Address	Saifai, Etawah, UP
Type of Sponsor	Research institution and hospital

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 Ramakant Rawat	Uttar Pradesh University of Medical Sciences	Isolation Ward, COVID-19 Hospital, Saifai, Etawah Etawah UTTAR PRADESH	6395926272 05688276509 ramakant.gsvm@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethical Committee, UPUMS, Saifai, Etawah	Approved	13/06/2020	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	Raj Nirwan Bati capsule	1. Mercury (Para) 2. Sulphur (Gandhak) 3. Gold (Sona) 4. Silver (Chandi) 5. Clamina Perpeta 6. Arsenic Trioxide (Hartal Bhasma) 7. Black pepper (Kaali Mirch) 8. Naag Damanti (Snake Plant) 9. Celery (Azwaiyan) 10. Zinc 11. Niramish (Mahamash oil) One Raj Nirwan Bati capsule of 125 mg (1 Ratti) twice a day empty stomach for 12 days
Comparator Agent	Placebo	Sugar gelatin capsule with 4 small balls of sugar twice a day empty stomach for 12 days

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	99.00 Year(s)
Gender	Both
Details	1. RT-PCR confirmed SARS-CoV-2 infected symptomatic patients admitted to the COVID-19 hospital of UPUMS 2. Patients falling in mild, moderate and severe category of COVID-19 illness 3.

	Patients more than 18 years of age

Exclusion Criteria

Exclusion Criteria	
Details	1. All critically ill patients of COVID-19 2. Patients not providing informed written consent for the study 3. Pregnant and lactating females 4. Patients of Chronic kidney disease (CKD) more than stage three 5. Asymptomatic cases 6. Study participants becoming critically ill during the course of intervention.

Method of Generating Random Sequence	Coin toss, Lottery, toss of dice, shuffling cards etc
Method of Concealment	Case Record Numbers
Blinding/Masking	Participant and Investigator Blinded

Primary Outcome

Outcome	Timepoints
Micro-biologically becoming RT-PCR negative for SARS-CoV-2	Micro-biologically RT-PCR results for SARS-CoV-2 shall be evaluated at baseline, day 6 and day 12

Secondary Outcome

Outcome	Timepoints
1. Persistence of symptoms beyond day 5 in mild cases and day 7 in moderate cases 2. Worsening of clinical features beyond day 5 except severe cases 3. Changes in bio-chemical parameters like LDH, CRP, SGPT, SGOT 4. Changes in haematological parameters 5. Radiological worsening.	These parameters will be evaluated on day 1, day 6 and day 12 after start of intervention.

Target Sample Size	**Total Sample Size=**60 **Sample Size from India=**60 **Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials
Phase of Trial	Phase 3
Date of First Enrollment (India)	30/06/2020
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)	Not Yet Recruiting
Publication Details	1. Raj kumar, Ramakant Yadav, Ramakant Rawat, Prashant Kumar Bajpai, Indra Kumar Sharma, Sushil Kumar, Prashant Yadav. Role of Raj Nirvan Bati in treatment of COVID19 RT-PCR positive cases. IJSRM June 2020; Accepted for publication 2. 1. Raj kumar, Ramakant Yadav, Ramakant Rawat, Prashant Kumar Bajpai, Indra Kumar Sharma, Sushil Kumar, Prashant Yadav. Raj Nirvan Bati (A novel ayurvedic preparation) in RT PCR positive COVID19 cases: An interventional study. IJMSCR June 2020;3(3)
Brief Summary	**Name of title:** To Determine the Efficacy of An Ayurvedic Preparation, Raj Nirwan Bati (RNB) on Symptomatic COVID-19 Patients: A Double-Blind Randomized Controlled Trial

Aim and Objectives:

1. To determine the efficacy of an ayurvedic preparation Raj Nirwan Bati (RNB) in treatment of symptomatic COVID-19 Patients.

2. To find out the duration of conversion of symptomatic patients to asymptomatic

3. To find out the duration for becoming RT-PCR negative

4. To evaluate the therapeutic response of RNB on bio-chemical and haematological profile.

Material and Methods:

Study design: A double-blind randomized controlled trial

Study units: Symptomatic patients diagnosed to be infected with SARS-CoV-2 and suffering from COVID-19 illness.

Place of study: Patients admitted in the indoor department of COVID-19 hospital at Uttar Pradesh University of Medical Sciences, Saifai, Etawah, Uttar Pradesh.

Study Duration: June 2020 onwards till the outcome variables in the study patients are met.

Sample Size: 30 cases in Intervention group and 30 in Control group

Study intervention tool: An ayurvedic preparation by the name of Raj Nirwan Bati (RNB).

Inclusion criteria:

1. RT-PCR confirmed SARS-CoV-2 infected symptomatic patients admitted to the COVID-19 hospital of UPUMS

2. Patients falling in mild, moderate and severe category of COVID-19 illness

3. Patients more than 18 years of age

Exclusion Criteria:

1. All critically ill patients of COVID-19

2. Patients not providing informed written consent for the study

3. Pregnant and lactating females

4. Patients of Chronic kidney disease (CKD) more than stage three

5. Asymptomatic cases

6. Study participants becoming critically ill during the course of intervention.

Methodology:

As an initial step, all suspected or laboratory confirmed patients coming to COVID-19 hospital of UPUMS, Saifai, Etawah shall be screened both clinically and by repeat laboratory tests to confirm the SARS-CoV-2 infection status and make the diagnosis of COVID-19. Those patients providing the consent and fall in mild, moderate and severe category of COVID-19 illness shall comprise our study units or subjects. Patients with fever, dry cough, myalgia and other non-specific symptoms will

be categorized as “mild illness” while “moderate illness” will have above symptoms along with dyspnoea on exertion or tachypnoea (Respiratory rate > 18/minute and oxygen saturation > 94%. The “severe illness” category of patients will be having any of the above sign and symptom with oxygen saturation between 90-94%.

After the initial screening, random allocation of these patients will be done in the intervention group and control group. Both groups or arms of the RCT will comprise of a sample of 30 patients in each study group. A battery of bio-chemical, haematological, micro-biological, radiological and other specific tests required for the management of co-morbid disease shall be performed on the selected study patients. The intervention group of patients will receive the Raj Nirwan Bati (RNB) in dose of 125 mg (1 Ratti) tablet twice a day with 5 to 10 ml honey/desi ghee empty stomach for duration of 12 days. On the other hand, the control group of patients will be administered placebo in the form of calcium tablet.

All the patients of both intervention and control group will receive the allopathic treatment as per standard protocols of the university. Regular vitals monitoring will be done of all the patients. Their repeat naso-pharyngeal swab will be taken for SARS-CoV-2 infection by RT-PCR examination on day 6 and 12 of RNB therapy. Routine investigations like complete blood count, Liver function tests, Renal function tests, LDH, CPK, CRP, Chest X-ray PA view, Ultrasonographic examination will be done at the time of admission and will be repeated on day 6 and day 12 of the illness.

The outcome variable of the study will be in the form of status of patients

1. RT-PCR report negative at day 6 of intervention

2. Persistence of symptoms beyond day 5 in mild cases and day 7 in moderate cases

3. Worsening of clinical features beyond day 5 except severe cases

4. Changes in bio-chemical parameters like LDH, CRP, SGPT, SGOT

5. Changes in haematological parameters

6. Radiological worsening.

Statistical Analysis:

Data thus collected shall be entered in Excel spreadsheet and analysed using spss statistical software (version 21) using appropriate tests.