

Identification of Ayurveda & Homeopathic Medicine for Clinical Management of Covid-19 need Clinical Trial

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Acknowledge to the Idea Originator:

The idea is to analyse the University Centre of Planning ,Integration & Correlation with Center of Integrative Health & Medical Science and Faculty of Pharmaceutical Science, Faculty of Ayurvedic Science & Faculty of Homoeopathic Science , Jayoti Vidyapeeth Women's University, Jaipur jointly made efforts to identify Ayurveda and Homoeopathy Medicines for Corona Clinical Management with modern medicine . **“Dr. Garg thoughts** “Drugs formed by the same source or same acts in different therapy pharmacopoeias which can be used as a single or with integrated approach to achieve better results”. “On the basis of same mode of antiviral activity of medicine “Remdesivir break replication of virus & Rhodiola rosea act same through enhance immunity”. **According to Hypothesis of “Dr.Garg Theory** same acts of medicinal plant “*Rhodiola rosea*” (root part) can be applicable for Homoeopathic & Ayurvedic Approaches .We can isolate efficient compound according to Homoeopathic and Ayurvedic Protocols and can apply for covid-19 patients. It will be more effective as an individual or Integrative form of research. **“Dr. Garg thoughts”**“Integrated research & strongly recommended and suggested either individual or with form of integration because both medicines are formed from same resource and actions are also same against corona-virus symptoms. Remdesivir in modern medicine (which is recommended by the Food Drug Administration as a nucleotide analog, specifically an adenosine analog, evidenced to have broad-spectrum activity against the single-stranded RNA viruses. Current research prospective of the drug on COVID-19 has revealed that it is effective against certain key enzymes of SARS-CoV-2, that caused COVID-19.and also used worldwide in Clinical Management of Novel Corona virus (COVID-19) in Ayurveda and Homoeopathic medicines which is used either individual or integration on the basis of “Dr. Garg thoughts”.

HYPOTHESIS:

“Dr.Garg Theory” based on same source of medicine either individual or integrative form **“A hope for a cure “against covid-19.**

Faculty of Pharmaceutical Science, Faculty of Ayurvedic Science & Faculty of Homoeopathic Science, Jayoti Vidyapeeth Women's University, Jaipur, **jointly made efforts to identify Ayurvedic and Homoeopathic Medicines for the Clinical Management of Corona with modern medicine.** **“Dr. Garg thinks”** that Remdesivir viewed as the most promising treatment for COVID-19, has known and potential side effects and there is no good evidence that Remdesivir reduced mortality in people with COVID-19. According to Hypothesis of **“Dr.Garg Theory”** medicinal plant **“*Rhodiola rosea*”** can be applicable for the treatment of Covid-19 through Ayurvedic and Homeopathic approaches. We can isolate effective compound according to Homeopathic and Ayurvedic Protocols and can apply for covid-19 management. *Rhodiola rosea* has shown marked anti oxidative, adaptogenic and antifatigue effect in the experimental study, this effect can be used to increase the immunity of the patient, can eventually be proved effective in the treatment of Covid-19. It will be more effective as an individual or Integrative form of research.“ Principal Investigator **Dr. Panckaj Garg** has suggested and recommended use of *Rhodiola rosea* in the treatment of corona individually as Ayurvedic and Homeopathic medicine or with Remdesivir (recommended by the Food Drug Administration as a nucleotide analog, specifically an adenosine analog, evidenced to have broad-spectrum activity against the single-stranded RNA viruses, currently proved effective against certain key enzymes of SARS-CoV-2, that caused COVID-19) as a integrated approach, on the basis of **“Dr. Garg thoughts”**. The need of integration is very important for the prevention and management during containment of Corona Virus (COVID – 19) infection. **Dr. Panckaj Garg** always strives for betterment of community and through this Hypothesis. He is very much committed for community health management and contemplating very seriously about the risk of COVID-19. He wants to serve the nation through effective treatment of Covid-19 with extensive research on herb *Rhodiola rosea*.

MODERN MEDICINE AND THEIR ASPECTS: In allied science or Modern Science used as Remdesivir it is a chemical compound. It is a broad-spectrum antiviral medication developed by the biopharmaceutical company Gilead Sciences. It is administered via injection into a vein useful for viral disease. Remdesivir, or GS-5734, is an adenosine triphosphate analog first described in the literature in 2016 as a potential treatment for Ebola. In 2017, its activity against the coronavirus family of viruses was also demonstrated.

Symptoms:

Remdesivir would target the replication of the virus. Baricitinib would try to quell the body's immune response, which is thought to be responsible for some of the damage to the organs that occur with COVID-19.

“Combination therapy may prove to be an important strategy in the treatment of COVID-19,” said according to “Dr.Garg Theory”. “Especially in severe disease where there may be need for the antiviral and immunomodulatory approach.”

Type -Small Molecule

Groups- Investigational

Description--Remdesivir, is an adenosine triphosphate analog first described in the literature in 2016 as a potential treatment for Ebola. In 2017, its activity against the coronavirus family of viruses was also demonstrated. Remdesivir is also being researched as a potential treatment to SARS-CoV-2, the corona virus responsible for COVID-19. Remdesivir was granted an FDA Emergency Use Authorization on 1 May 2020. **Indication**--Remdesivir has an FDA Emergency Use Authorization for use in adults and children with suspected or confirmed COVID-19 in hospital with an SpO₂ ≤94%. Remdesivir was originally investigated as a treatment for Ebola virus, but has potential to treat a variety of RNA viruses. Its activity against the coronavirus (CoV) family of viruses, such as SARS-CoV and MERS-CoV, was described in 2017, and it is also being investigated as a potential treatment for SARS-CoV-2 infections.

Mechanism of action--Remdesivir is a nucleoside analog that is expected to inhibit the action of RNA polymerase. By incorporating into RNA, additional nucleotides cannot be added, terminating RNA transcription. Viruses with mutations in RNA polymerase to develop partial resistance to remdesivir have been shown to be less infective.

AYURVEDIC ASPECTS AND THEIR PROPOSED STUDY:

In Traditional medicine in root of *Rhodiola rosea* is used for cough, cold, breathlessness fever, by local people. We can make a hypothesis that *Rhodiola rosea* is expected to reduce symptoms of Covid 19 which majorly comprises of fever, cough, fatigue and breathlessness. It may also prevent the patient to land in respiratory emergency condition.

In Ayurveda **Jwara disease** is described very minutely covering all types of fever. A symptom of **Vatashleshmic Jwara** which is one of the types of **Dwandaja jwara** has the close similarity to the Covid 19 symptoms. **Acharaya Charak has described Vatashleshmic Jwara as** follows:

Symptoms

- Feeling cold
- Heaviness
- Drowsiness,
- Fatigue
- pain in joints
- feeling of stiffness of head
- cold
- cough
- moderate rise in body temperature

Rhodiola rosea can be proved effective in all symptoms of **vata-shleshmic jwara**. This herb must be of **katu rasa, katu vipaka and ushnvirya**, as this can be assumed from its effects.

Few examples of effect of herb with their chemical constituents

Ephedrine extracted from *Sida Cordifolia* also has heart rate and blood pressure lowering effect.

Bromexine extracted from *Adhatoda Vasaka* has bronchodilator effect.

OBJECTIVE OF RESEARCH

- To See the Effect of *Rhodiola rosea* on Corona (Covid 19) with the combination of Remdesevir with Ayurvedic medicine prepared by *Rhodiola rosea*.
- Study On Covid Patients with Cure by *Rhodiola rosea* for Saving the Human Life.
- To Develop A New Drug In The History Of Ayurveda.

Preparation of trial Medicine

Roseroot (*Rhodiola rosea L.*) belongs to plants revealing adaptogenic properties, which are attributed to the presence of specific phenolic compounds and are reflected mainly as antioxidant activity. Dry extracts of rhodiola will be extracted by the most common method of extraction i.e

Dry extract (DER 1.5-5:1), extraction solvent ethanol 67-70% v/v. This is the most common method to extract chemical constituents from herbs. Capsules filled with 100mg, 150mg and 200mg will be given to patients of respective three trial groups to see the efficacy of *Rhodiola rosea*.

Materials and Methods:

As per “Dr Garg hypothesis “The Proposed and suggestive work study will be carried out in any research centre as per the own guidelines or any Ayurvedic Pharmacy for this pandemic world wide problem so we will be proceeds anywhere.

Selection of samples: Minimum of Sixty (60) cases of Covid 19 fulfilling the inclusion criteria as given below will be included in the study.

INCLUSION CRITERIA:

1. Age criterion is from 18 yrs to 55 yrs
2. Covid 19 RT- PCR test positive Asymptomatic Patients
3. Covid 19 RT- PCR test positive patients with fever, cough and fatigue
4. Covid 19 RT- PCR test positive patients with fever, cough, fatigue and mild breathlessness but Spo2 is more than 90% and no radiological changes of Pneumonia in chest X ray

EXCLUSION CRITERIA:

1. Patients of less than 18yrs of age and more than 55yrs of age
2. Severe cases of Pneumonia with significant radiological changes in chest- Xray
3. Covid 19 patients with co-morbidities like Diabetes Mellitus, Hypertension, coronary artery disease, Respiratory ailments
4. Pregnant ladies

Clinical Trial

All 60 patients will be divided into three groups comprising of 20 patients each

Group1 will be given 100mg of Rhodiola root extract in capsule form two times a day after meals with water for 2 weeks

- **Group2** will be given 150mg of Rhodiola root extract in capsule form two times a day after meals with water for two weeks
- **Group3** will be given 200mg of Rhodiola root extract in capsule form two times a day after meals with water for two weeks

PARAMETERS OF ASSESMENT:

Total 60 patients from all the three groups will be examined clinically daily on the basis of following sign and Symptoms:

- Fever (by measuring body temperature 6 hourly)
- Cough
- Fatigue
- Breathlessness
- Auscultation of chest to assess any findings of pneumonia
- SPO₂ measurement, if breathlessness is present

Investigation to assess progress

RT- PCR test for Covid-19 should be done on third day or fifth day of treatment depending upon the improvement of symptoms.

HOMEOPATHIC ASPECTS AND THEIR PROPOSED STUDY

Rhodiola rosea, is a medicinal plant with demonstrated nontoxic substance properties, has recently been reported to contain active compounds with antiviral, antimicrobial activity.

The goal of this study was to measure the antiviral properties of the bioactive metabolites of *Rhodiola rosea* in the persons who are affected by covid-19. *Rhodiola* roots contain polyphenols, rosavin, rosin, rosarin, organic acids, terpenoids, phenolic acids and their derivatives, flavonoids, anthraquinones, alkaloids, tyrosol, and salidroside. Polyphenols also work as anti-oxidant and anti-cancer. In older study on polyphenol improvement in the reduction of the viral concentration was observed.

Rhodiola rosea common name golden root, rose root, roseroot, Aaron's rod, Arctic root, king's crown, lignum rhodium, orpin rose is a perennial flowering plant in the family Crassulaceae. It is found at high altitudes in the Arctic and mountainous regions throughout Europe and Asia. It has historically been used to treat a range of conditions, including fatigue, depression and anxiety, impotence, and nervous system disorders. *Rhodiola rosea* has also received attention for its potential adaptogenic and ergogenic properties including the enhancement of physical and mental performance and reduction of fatigue.

Rhodiola rosea and polyphenolic bioactive compounds from the plant, such as rosavin, salidroside, syringin, triandrin, and tyrosol, have been reported to exert beneficial effects against several pathogens. For example, flavonoids isolated from the roots of *Rhodiola rosea* have been shown to inhibit the activity of neuraminidases from *Clostridium perfringens* and influenza virus, and exert anti-influenza virus activities in vitro. More recently, studies have shown that *Rhodiola* inhibits dengue virus growth in blood by regulating the innate immune response genes, RIG-I, MDA5, and ISG, to promote an effective antiviral immune response. *Rhodiola rosea* and its potential as a therapeutic strategy against a variety of infectious diseases.

COVID-19 affects different people in different ways. Most infected people will develop mild to moderate illness and recover without hospitalization but in some patients it developed and produces life threatening symptoms.

Most common symptoms:

- Fever
- Dry cough
- Tiredness

Less common symptoms:

- Aches and pains
- Sore throat
- diarrhoea
- Conjunctivitis
- Headache
- Loss of taste or smell
- A rash on skin, or discolouration of fingers or toes

Serious symptoms:

- Difficulty breathing or shortness of breath
- Chest pain or pressure
- Loss of speech or movement

On average it takes 5–6 days from when someone is infected with the virus for symptoms to show, however it can take up to 14 days.

Randomly group will divided into two groups, give 8 globule/day of Rhodiola rosea 200 (n=20, 10 female, 10 male) or placebo (n=20, 10 females, 10 males) for 15 days from the day of infection detected by report of covid 19 positive. Blood serum samples will collect the day before administration of medicine.

The purpose of this study is to see the action of antiviral activity of *Rhodiola rosea* on covid 19 symptoms as mentioned above This work is done with the help of clinical trial of the patients those affected by corona virus. It is a integrated approach of ayurveda and homeopathy.

Duration of study: 1 month

Material & method:

STUDY DESIGN:

As per “Dr Garg hypothesis”, This Proposed and suggestive work for this pandemic word wide problem so we will be proceeds in any research centre as per the own guidelines or any Homeopathic Pharmacy for community health management and contemplating very seriously about the risk of COVID-19. We include the all age group persons in the study start from 18 year to 70 year. *Rhodiola rosea* roots having for the study and follows all the protocol of homeopathic pharmacopeia. The bioactive content of the *Rhodiola rosea* root powder will take and triturated by the method of trituration as per the chemical composition of root extract it's useful for boost the immunity, anxiety treatment and also as antiviral medicine.

Study procedures will review and approve by research centre and we start to make medicine under the guidance of guideline given by CCRH & ICMR. We will take 40 persons for clinical trial in **INCLUSION CRITERIA:**

- Take only corona positive patient & medicine will be given along with ayurvedic medicine.
- Age group: 18-70 year
- Male and female both includes in trial
- Along with medication maintenance of diet and regimen
- Hygiene education includes in clinical trial for stop the spread of virus on community.

EXCLUSION CRITERIA:

- Corona positive along with other disease like diabetes, immunosuppressive disorder etc not taking under the study.
- Age: below the 18 year excludes from the study
- Children not includes under the trial.

OBSERVATION OF THE STUDY:

Observation will be done under the supervision of doctor. Medicine would be administered in the patient with combination of Remdesivir + ayurvedic medicine of same+ *Rhodiola rosea* 30 gives on tongue dose with repetition on demand of patient symptoms and lab investigation report.

As per the clinical trial of this medicine we will inform our research result after 30 days along with the proper documentation.

OBJECTIVE OF RESEARCH

- To See the Effect of *Rhodiola Rosea* on Corona (Covid 19) with the combination of Remdesivir + Homeopathic (*Rhodiola rosea* 30).
- Study On Covid Patients with Cure by *Rhodiola Rosea* For Saving The Human Life.
- To Develop A New Drug In The History Of Homeopathy

PREPARATION METHOD:

As per rules and regulation of homeopathic drug preparation method

1. Selection of raw material that is root of plant *Rhodiola Rosea* dried in shed not sunlight that is coz of precaution.
2. Trituration of raw material by grinding with mortar and pestle traditionally this was done manually by grinding the material in a mortar and pestle. We do this work with a mechanical device called a ball mill. This is similar in design to something you may be more familiar with called a rock polisher, or rock tumbler. The ball mill consists of a cylindrical porcelain jar with a tight lid. The material we want to triturate is placed into the jar along with 99 times as much lactose and the extremely hard "balls" which will grind the material. (Actually we now use small cylinders rather than the balls used originally. Small cylinders grind better than balls.) In trituration, what we are doing is preparing a dry dilution. We take 1 gram of material and 99 grams of lactose, and mix them together carefully before adding them to the ball mill. When the ball mill has run for at least several hours, the material is removed and is designated as the 1C level of potency. One gram of the 1C is mixed with 99 grams of lactose and put back into a clean ball mill. After grinding the material for at least several hours, the material is carefully removed and is designated the 2C potency. In the same way, 1 gram of the 2C is mixed with 99 grams of lactose and ground in the ball mill and becomes the 3C potency. Homeopathic materials are therefore triturated for many hours to produce the final 3C triturate which is then used to prepare liquid potencies. One gram of the 3C is dissolved in a total of 100 milliliters of a water and alcohol solution. In this way even substances which are completely insoluble are turned into liquid preparations which may be treated just like liquid preparations of soluble materials.

3. Preparation of liquid potencies by dilution and succession: For the preparation of liquid potencies from triturate part, there is a two-part process at each step. First, we prepare a one to one hundred dilution of the solution and then we succuss this new dilution vigorously at each step. (Succussion is the forceful pounding of the liquid dilution against a firm but resilient surface.) WE TAKE THIS PROCESS VERY SERIOUSLY for the betterment of community health management and contemplating very seriously about the risk of COVID-19. THIS IS THE CORE FUNCTION AT ANY HOMEOPATHIC PHARMACY as per own guidelines can be proceed their suggested proposed study. It is so important that these steps be done correctly that we will do not allow one person to perform them acting alone. It is our experience that each and every potency should be vigorously succussed in order to fully develop its potential. We have designed a new semi-automatic potentizer which ensures that each of these succussions is performed with the same number of strokes and with the same force on each stroke to ensure that every medicine we make is of the highest quality.

4. Medication of blank pellets with liquid potencies here we can prepare potency 30c as per the need of clinical trial of viral disease.

5. Drying of medicated pellets

6. Packaging of medicated pellets in vials for use by homeopathic doctors for the patients.

Conclusion as an Authorization for their Future prospective proposed study: This research proposal is being submitted to AYUSH Ministry, Govt.of India and CCRAS & Central Council for Research in Homoeopathy (CCRH) to focus on the development of an effective treatment as well as preventive therapy for Covid-19 patients. In today's epidemic outburst circumstances, there is a need of Ayurveda, Modern Science and Homoeopathy to come together to cure COVID-19. The proposed study According to "Dr.Garg Hypothesis" We will determines the efficacy of *Rhodiola rosea* root as efficient Integrative medicinal approach along with Ayurveda, Homeopathy and allopathy. At the end of 2019 a novel virus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), causing severe acute respiratory syndrome expanded globally from Wuhan, China. In March 2020 the World Health Organization declared the SARSCov-2 virus a global pandemic. We performed a narrative review to describe existing literature with regard to Corona Virus Disease 2019 (COVID-19) epidemiology, pathophysiology, diagnosis, management and future perspective.

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