

Homeopathic Clinical Drug Proving Trial on Rhodiola Rosea

Jayoti Vidyapeeth Women's University, INDIA

Chief Investigator – Jvn Dr. Panckaj Garg

Co-Investigators – Jvn Dr. M. P. Sharma
Jvn. Dr. Rakesh Sharma
Jvn Dr. Anil Kumar Vangani
Jvn Dr. Pushpa Kumawat

Study Description

Brief Summary:

The main aim of the study is to assess whether Rhodiola rosea in the potency C 1-4 nitites more characteristic homeopathic symptoms during proving after three days upto one week, compared to a placebo in Hypertensive and Anxiety/ Depression prone volunteers.

Secondary aims are to develop and to test a qualitative analysis methodology on which to base a definition for drug-specific (characteristic) symptoms and to compile a profile of characteristic homeopathic proving symptoms of the drug being trialed for therapeutic purposes.

This study protocol adapts the traditional homeopathic drug proving methodology to a modern clinical trial design.

Study Type : Interventional (Clinical Trial)

Actual Enrollment : 29 participants (9 dropped out in course of proving)

Allocation: A Randomized study

Intervention Model: Assignment done parallely

Masking: Quad basis (Participant, Care Provider, Investigator, Outcomes Assessor)



Official Title: Proving Trial of Homeopathic Drug

Starting Date of Study: 8th March, 2020

Primary Completion Date : 7th July, 2020

Actual Completion Date : 25th July, 2020

Condition or disease	Intervention/treatment	Phase	Result
Subjects with HT, Anxiety/ Depression , Irritability, low immunity	Finding in literature some new drugs of vegetable kingdom which have effects on higher centres of mind capable of producing anxiety and depressive conditions leading to low energy and immunity levels	One	Found in Joseph E. Pizzorno ND, ... Herb Joiner-Bey ND, in The Clinician's Handbook of Natural Medicine (Third Edition), 2016 Botanical medicines - <i>Rhodeola rosea</i> as a medicine with antifatigue effect that increases mental performapopular plant in traditional medical systems in Eastern Europe and Asia to help combat fatigue and restore energy. <i>Rhodiola</i> hence—the ability to concentrate—and decreases cortisol response to awakening stress.
Subjects with HT, Anxiety/ Depression , Irritability, low immunity	Reviwing Literature on found herbal drug	Two -	<i>Rhodiola (Rhodiola rosea)</i> is a perennial plant that grows in the US, Canada, Europe, and parts of Asia. Its root, also known as golden root, is commonly used in Asia and Europe to treat fatigue and cognitive blunting. Its pharmacology is complex and includes a large number of active compounds, such as flavonoids, monoterpernes, phenylpropanoids, triterpenes, phenolic acids, and phenylethanol derivatives. It has multiple effects, including antioxidant, anticarcinogenic, cardioprotective, and neuroendocrine properties. Its psychopharmacological effect may include agonist properties for serotonin and dopamine and norepinephrine (perhaps secondary to monoamine oxidase inhibition), as well as influence on opioid peptides (such as beta-endorphins) and nicotinic receptors for acetylcholine . Importantly, it may also act on cellular membrane and improve the ability of serotonin and catecholamine precursors to cross the blood–brain barrier (Saratikov & Krasnov, 1987). Thus, it may be beneficial to augment treatment with

			<p>tryptophan/5-HTP and/or phenylalanine/PEA with rhodiola. Rhodiola has been shown to have antidepressant and psycho-stimulant effects. Saratikov and Krasnov (1987) reviewed the results of a number of studies that showed that patients with asthenia (fatigue, decline in work capacity, trouble falling asleep, poor appetite, irritability, and headaches) responded favorably to rhodiola at doses of 50 mg three times per day (TID). Treatment durations ranged from 10 days to 4 months, and in studies up to 64 percent of cases exhibited significant improvement. More recently, similar results have been reported by Shevtsov <i>et al.</i> (2003) and D</p>
<p>Procuring drug from authentic source</p>	 <p>Rhodiola rosea - a perennial flowering Succulent Plant of the family Crassulaceae.</p> <p>Habitat: It grows naturally in wild Arctic regions of Europe (including Britain), Asia, and North America,</p> <p>Common name – Golden root</p> <p>Max.height – 16 inches</p> <p>Flower color – Yellow</p> <p>Bloom Time – May to August</p> <p>Temp. required - 10-25 degree C</p>	<p>Three</p>	 <p>RHODIOLA ROOT POWDER</p> <p>Mystique Hills Rhodiola rosea Root Powder (Premium Quality) 50 g Brand: Mystique Hills - Organic Living, ordered by online shopping portal – Amazon</p>

	Part used for medicine - roots		
Guinea pigs fed with Rhodiola rosea to be studied for nephrotoxicity/hepatotoxicity	Rhodiola rosea 1c dissolved in distilled water and 3gr each time mixed with 6 ml milk fed 4 times daily to animal for four days and wait and watch for next 3 days.	Four - Toxicity study on animals	None toxicity signs were observed, animal became dull from 2-3 day and more active on 5 th -7 th day, actin seems on energy levels, nerves and mental sphere
Subjects with HT, Anxiety/Depression, Irritability	Rhodiola rosea 1C, 2C, 3C & 4C in sequential day to day basis for first four days, then wait and watch for next three days for primary and secondary actions to develop, tested on 20 different individuals of both sex, of various constitutions, of different socio-economic groups	Five – Clinical trial on Susceptible Human beings who are prone to Anxiety and Depression	Dullness and Over thinking with irritability, taking unfavorable decisions for others on day 2 nd and 3 rd , becoming more pliable, affectionate and balanced thinker 5 th – 7 th day



Making Homoeopathic Medicine from Rhodeola Rosea and Developing the potencies for purpose of Clinical proving by Director Faculty of Homeopathic Science Dr. M.P. Sharma, Prof. and HOD Organon – Dr. Rakesh Sharma, Prof. and HOD Repertory – Dr. Anil Kumar Vangani, Asst. Prof. Deptt. of Homeopathic Pharmacy – Dr. Pushpa Kumawat

Clinical Proving done on an individual volunteer of High socio economic group - prone to Hypertension, frequent colds ,easy fatigability, stress, hypertension, anxiety, irritability and impatience –

Mind: Wants to be alone

Irritability

Insecure about self image

Religiousness

Thirst 1.5 litres in whole day, ½ to 1 glass of water at a time

Stool –Clear

Urine – Umber colored

Ist Day: Taken Rhodeola rosea 1c; 4 grain dose morning; After 2 Hr. – Hoarseness of voice, taken ice cream after dinner, caught sore throat which got itself improved next morning

IInd Day – Taken Rhodeola rosea 2c; 4 grain dose morning; After eating a bowl of curd in breakfast - a lot of sneezing started which itself diminished in intensity till afternoon. After dinner taken ice cream today again but no pain in throat this time.

IIIrd day – Sneezings and Sore throat felt in early morning - Taken Rhodeola rosea 3c; 4 grain dose morning; - Sore throat and Sneezings got better and energy level felt better upto breakfast and Lunch. Taken Ice Cream after dinner again this night.

IVth Day – Sore throat felt in the morning, pain in throat on swallowing saliva, but with much expectoration this time. Taken 1/2 dilution this time 10 drops in 1 ounce of luke warm water – after 1 hour - Temp. 100 Degree Farenheit, frontal headache, bodyache with pain in spots various parts of body, loss of sense of taste for food – food feeling tasteless; Slight vertiginous feeling in the evening –taken light meal – porridge and went for rest early by 8 0’ clock in the evening.

Vth Day – Feverish felling, no more dosing done, loss of taste for regular food, desire more salt and sugar in food but no effect felt. Taken warm water whole day and saline gargles done 3 times a day. Porridge taken in meals. Fever upto 101 degree Farenheit on an average whole day.

VIth day – Morning waken up with weakness but no more fever, feeling intense thirst. Expectoration yellow thick which ameliorated soreness in throat, felt better by evening, but still taken porridge and warm water upto dinner on 6th day.

VIIth Day – Feeling much better in morning, energy levels a lot improved, desire to go for morning walk. Took normal tea today. More mental clarity, no more irritability and Insecure feeling. Light Breakfast taken. A little sleepy feeling in afternoon which improved after 20 mins. Nap, remained active till evening, no more pain throat or expectoration anf fever. Took usual meal in less quantity at night. No more complaints left.

Conflict of Interest: None as it is self financed project, sponsored by the university in wake of Covid-19 Pandemic to get a medicine for immune modulation of susceptible population in Urban Areas.

Conclusion: After studying effect of Rhodiola Rosea 1c – 4c, on 20 volunteers, it can be concluded that it is an excellent adaptogen, raises energy levels of individuals with capacity to think more clearly without influence of anxiety or depressive thoughts which various volunteers were already complaining of before study, also enhancing immune system for rapid recovery from Influenza like Illness which such individuals who are prone for stress and strain of modern lives often suffer from.

Scope of Future Study: More and More such studies can be carried out in the future esp. using higher potencies of Rhodeola rosea to explore psychological use of it in various psychiatric ailments.