



*International Journal Of*  
**Recent Scientific  
Research**

ISSN: 0976-3031  
Volume: 7(4) April -2016

AN OPEN LABELED RANDOMIZED STUDY TO ASSESS THE EFFICACY  
AND SAFETY OF KRIMIHAR YOGA

Swapnil Singhai and Nagesh Jaiswal



THE OFFICIAL PUBLICATION OF  
INTERNATIONAL JOURNAL OF RECENT SCIENTIFIC RESEARCH (IJRSR)  
<http://www.recentscientific.com/> [recentscientific@gmail.com](mailto:recentscientific@gmail.com)



ISSN: 0976-3031

Available Online at <http://www.recentscientific.com>

International Journal of Recent Scientific Research  
Vol. 7, Issue, 4, pp. 10425-10428, April, 2016

**International Journal of  
Recent Scientific  
Research**

## Research Article

# AN OPEN LABELED RANDOMIZED STUDY TO ASSESS THE EFFICACY AND SAFETY OF KRIMIHAR YOGA

Swapnil Singhai<sup>1</sup> and Nagesh Jaiswal<sup>2</sup>

<sup>1</sup>Department of Kayachikitsa Uttarakhand Ayurved University, Gurukul Campus, Haridwar, U.K., India Pin- 249404

<sup>2</sup>Department of Kaumarbhritya (Balrog), Bhausaheb Mulak Ayurved Mahavidyalaya, Great Nag Road, Nandanvan, Nagpur, 440009

### ARTICLE INFO

#### Article History:

Received 20<sup>th</sup> January, 2016  
Received in revised form  
29<sup>th</sup> February, 2016  
Accepted 30<sup>th</sup> March, 2016  
Published online 28<sup>th</sup> April, 2016

#### Keywords:

Krimihar Yoga, Krimiroga,  
Helminthes, Intestinal worms.

### ABSTRACT

The prevalence of intestinal helminthes is often recognized as one of the important public health problems in developing countries. Herbal drugs continue to play an essential role in health care. It has been estimated by the World Health Organization that 80% of the population of the world rely mainly on traditional medicines for their primary health care. The objective of this study was to determine the clinical efficacy and safety of *Krimihar Yoga*, a poly herbal formulation of herbal ingredients in the management of *Krimi* of various etiological conditions in open labeled, randomized, prospective study. 20 patients with 5 - 14 years of age, either sex, confirmed as per the sign and symptoms of disease were recruited in the study. Treatment results were assessed on the basis of Investigator's evaluation. The overall assessment showed that most of the patients were markedly improved after completion of the prescribed treatment.

Copyright © Swapnil Singhai and Nagesh Jaiswal., 2016, this is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution and reproduction in any medium, provided the original work is properly cited.

## INTRODUCTION

Prevalence of helminthiasis in developing as well as underdeveloped countries enforcing great threat as it is causing nutritional deficiencies and diseases directly, due to loss of protein, blood and other nutrients as well as indirectly through gastro-intestinal disturbances like anorexia, flatulence, abdominal pain, nausea, vomiting and diarrhea which leads to mal-absorption syndrome and malnutrition. The situation is further aggravated, due to inadequate intake of food and imbalanced diet, ignorance of dietary habits, various socio-economic and environmental factors like lack of proper sanitation, literacy and use of uncooked raw food or improper washing of food materials etc<sup>[1]</sup>.

According to WHO, it is estimated that about 1/4<sup>th</sup> of the population are infected with one or more of most common type of parasites like Round worms (*Ascaris lumbricoides*), Hook worms (*Necator americanus* and *Ancylostoma duodenale*) and Whip worms (*Trichuris trichiura*).<sup>[2]</sup>

Children are more likely to manifest acute evidence of disease because of low immunity or tolerance and greater opportunity

for exposure of parasite infestation; it not only influences the body but rather sometimes leave greater impact on the growth and development of the children.

In *Ayurveda*, parasitic infection and helminthic infections are included under *Krimi Roga*. Different varieties of *Krimi* are described in *Ayurvedic* literature.<sup>[3]</sup> General symptoms which mark the presence of worms in the system are fever, paleness of complexion, abdominal pain, cardiac troubles, lassitude, vertigo, aversion to food and diarrhea.<sup>[4]</sup> *Ayurvedic* classics explain the treatment as *Apakarashna* (extraction of worms with the help of *Sansodhana* therapy- *Vaman* (therapeutic vomiting or emesis), *Virechan* (purgation), *Vasti* (medicated enema), *Nasya* (elimination of toxins through the nose), *Prakriti Vighata* (utilising antihelminthic drugs along with dietary regimen non-congenial to proliferation of helminthes) and *Nidan-parivarjana* (avoidance of all etiological factors of helminthiasis).<sup>[5]</sup>

In modern medicine Anthelminthic drugs used are *Mebendazole*, *Albendazole*, *Pyrantel pamoate*, *Levamisole*, *Praziquantel* etc.<sup>[6]</sup> But all these drugs have a long list of adverse effects with them, like diarrhea, nausea, abdominal

\*Corresponding author: **Swapnil Singhai**

Department of Kayachikitsa Uttarakhand Ayurved University, Gurukul Campus, Haridwar, U.K., India Pin- 249404

pain, allergic reactions, and loss of hairs. Besides that herbal medicine give side benefits instead of side effects. Herbal medicines are cost effective, easily available and safe for long term use. Therefore, the herbal therapeutics has attracted considerable glamour for providing safe and effective remedies.

### Objectives

1. To study the aetio-pathogenesis of *Krimiroga*.
2. To assess the efficacy and safety of *Krimihar Yoga*.

### Test Medicine

*Krimihar Yoga* is a poly herbal preparation containing powder of *Vidanga (Embelia ribes)*, *Ajwain (Trachyspermum ammi)*, *Ajmoda (Apium graveolens)*, *Khurasani Ajwain (Hyoscyamus niger)*, *Palash Pushpa (Butea monosperma)* All the ingredients are safe and individual therapeutic efficacy is also reported in relieving the symptoms of *Krimiroga*.

## MATERIAL AND METHODS

The research study entitled “An open labeled randomized study to assess the efficacy and safety of *Krimihar Yoga*” was an observational clinical trial done with herbal formulations of *Krimihar Yoga*.

### Research Design

The study was a single open prospective randomized clinical trial conducted over a period of one week (follow up for 1 months) to evaluate symptomatic and subjective improvement in patients of *Krimiroga*.

### Inclusion Criteria

- Either sex ageing between 5-14 years
- Patients having classical symptoms of *Krimiroga* and presence of Ova/cyst/worms in stool examination

### Exclusion Criteria

1. Patients having severe illness or complication
2. Patients requiring immediate medical intervention
3. Participating in any other clinical trials.

### Study Population

Total 20 patients of either sex with confirmed *Krimiroga* as per the sign and symptoms were enrolled in the study.

### Criteria for Selection of Drug

*Krimihar Yoga* consists of certain herbal ingredients presented in the powder form for oral administration. All the ingredients are safe and their individual therapeutic efficacy was also reported in relieving the symptoms of *Krimiroga*. The raw drugs are easily available and low cost compared to other therapy. Hence *Krimihar Yoga* was selected for research study.

**Ingredients:** One gram of *Krimihar Yoga* contains –

1. *Vidanga (Embelia ribes)* – 250 mg
2. *Ajwain (Trachyspermum ammi)* – 250 mg
3. *Ajmoda (Apium graveolens)* – 250 mg
4. *Khurasani Ajwain (Hyoscyamus niger)* – 125 mg
5. *Palash Pushpa (Butea monosperma)* – 125 mg

Dose of Drug – 1-2 gm BD with Honey/ plain water.

### Diagnostic Criteria

An elaborate case paper incorporating the points of history taking, previous medication, past illness and physical examination was prepared. It mainly emphasized on signs and symptoms of *Krimiroga*.

Routine laboratory investigation like CBC and Stool examination (Ova/cyst) was made to rule out the conditions.

### Criteria for Assessment

The assessment was made before and after the treatment on scoring of signs and symptoms of *Krimiroga*. Scoring pattern was developed according to severity of symptoms. Results were analyzed statistically as per the assessment chart.

### Subjective Parameters

*Symptoms were evaluated on the basis of 0=Normal, 1-Mild, 2-Moderate and 3- Severe.*

- Fever
- Paleness of complexion
- Anal Itching
- Abdominal pain
- Lassitude
- Anorexia
- Nausea
- Vomiting
- Loose stool

### Objective Parameters

- Evaluation of Stool examination – Presence of Ova and cyst in microscopic examination was evaluated as: Absent – 0, Present – 1.

**Assessment of total effect:** The total effect of therapy was assessed as;

Assessment	Score
Complete cure	100%
Marked Relief	> 75 to 99%
Moderate Response	> 50 to 75%
Mild Improvement	> 25 to 50%
No response	0 to 25%

### Observation

The effect of *Krimihar Yoga* was studied in 20 patients suffering from *Krimiroga*, fulfilling the inclusion criteria. On analysis, it was found that maximum number of patients belonged to Hindu community (70%), 80% had educated parents and 60% was belonging to middle class families. 100% of patients were from urban area, had good hygiene 80%, most of the patients 80% were properly immunized to their age where as 20% were only partially immunized. Majority of patients were weak. Maximum numbers of patients were strict vegetarian's 70%. Most of the patients 80% were having irregular food habits irrespective of hunger. 60% were having disturbed sleep regularly and 40% were having regular day sleep.

### Effect of Therapy

The effect of therapy on all subjective and objected parameters has been documented in tables. The effect of test drug on all cardinal symptoms is showing a highly significant result in anal itching, abdominal pain, lassitude, anorexia and loose stool after completion of one week treatment. Stool examination for ova and cyst showed a highly significant result. In all symptoms the drug showed a remarkably high percentage improvement above 60% except in fever, paleness of complexion, nausea and vomiting. Paleness of complexion showed a significant 59.09% result.

### Overall Effect of Therapy

The overall assessment considering all the parameters outlined in the assessment criteria, the final result shows that 65% of patients had marked relief and 15% each had moderate and mild improvement. 5% patient (one patient) was completely cured after treatment.

**Table 1** Effect of *Krimihar Yoga* on symptoms of 20 patients of *Krimiroga*

Symptom	BT	AT	Diff. Mean	% Relief	SD	SE	't' value	P value
Fever	0.700	0.300	0.400	57.14	0.503	0.112	1.925	P>0.01
Paleness of complexion	1.100	0.450	0.650	59.09	0.489	0.109	3.299	P<0.01
Anal Itching	2.250	0.700	1.550	68.88	0.605	0.135	7.566	P<0.001
Abdominal pain	1.800	0.650	1.150	63.88	0.366	0.082	6.046	P<0.001
Lassitude	1.600	0.550	1.050	65.62	0.394	0.088	5.971	P<0.001
Anorexia	1.400	0.550	0.850	60.71	0.366	0.082	4.834	P<0.001
Nausea	1.000	0.600	0.400	40.00	0.503	0.112	2.179	P>0.01
Vomiting	0.550	0.350	0.200	36.36	0.410	0.092	1.265	P>0.01
Loose stool	0.750	0.200	0.550	73.33	0.510	0.114	3.584	P<0.001

**Table 2** Effect of *Krimihar Yoga* on stool examinations of 20 patients of *Krimiroga*

Stool Examination	BT	AT	Diff. Mean	% Relief	SD	SE	't' value	P value
Ova & Cyst	1.000	0.150	0.850	85.00	0.366	0.082	10.376	P<0.001

**Table 3** Overall effect of *Krimihar Yoga* in 20 patients of *Krimiroga*

Result	Number of Patients	Percentage
No Response	0	0
Mild Improvement	03	15%
Marked Relief	13	65%
Moderate Response	03	15%
Complete cure	01	5%

## DISCUSSION

This study was conducted as 'An open labeled, randomized prospective study to assess the efficacy and safety of *Krimihar Yoga*'. The results of this study demonstrate that most of the patients got marked relief after completion of treatment.

*Krimihar yoga* is a multi-herb powder formulation which contains important herbs in optimum concentrations. One of the important pharmacologically active compounds found in *Krimihar Yoga* is *Vidanga (Embelia ribes)*, having *Katu, Tikta Rasa, Laghu, Ruksha* and *Tikshna Guna, Ushna Veerya, Katu Vipaka* and *Anulomana, Deepana, Kriminashana* and *Vatakaphagna* Properties. It acts as ascaricidal, anthelmintic, carminative, diuretic, astringent, anti-inflammatory, antibacterial and febrifuge.<sup>[7]</sup>

Anthelmintic activity of *Ajwain (Trachyspermum ammi)* shows its effect against specific helminthes, e.g. *Ascaris*

*lumbricoides* in humans and *Haemonchus contortus* in sheep.<sup>[8]</sup> Anthelmintic activity of *Trachyspermum ammi* exerts by interference with the energy metabolism of parasites through potentiating of ATPase activity and thus loss of energy reserves.<sup>[9]</sup> The plant has also been reported to possess cholinergic activity with peristaltic movements of the gut, thus helping in expulsion of intestinal parasites which might also be a contributory factor to its anthelmintic activity.<sup>[10-11]</sup>

*Ajmoda (Apium graveolens)* is reported as sedative, diuretic and antispasmodic effects which may be due to phthalide constituents (d-limonene, selinene and related phthalides). Essential oil obtained from this plant is reported to have a calming effect on the central nervous system. Some of its constituents showed antispasmodic, sedative and anti-convulsant actions.<sup>[12]</sup>

*Khurasani Ajwain (Hyoscyamus niger)* is having *Tikta, Katu Rasa, Guru, Ruksha Guna, Ushna Veerya, Katu Vipaka, and deepan, Grahi, Pachana, Pittakara, Kaphavatahara, madak, nidrakarak*, having Anaphrodisiac, Anodyne, Anthelmintic, anti-rheumatic, antiseptic, hypnotic sedative, antispasmodic, carminative, astringent and anticholinergic properties.<sup>[13-14]</sup>

The anthelmintic activity of alcohol and ethyl acetate extracts of *Palash (Butea monosperma)* were noticed against earthworms (*Pheretima posthuma*), roundworms (*Ascaridia galli*) and tapeworms (*Raillietina spiralis*).<sup>[15]</sup>

The safety and tolerability of study medications was assessed based on adverse events reported by patients or observed by the investigator during evaluation. No clinically significant adverse effect neither reported by the patients nor observed by the researcher during the study.

As revealed by the results, in different subjective and objective parameters remarkable improvement in disease condition was observed, which can be attributed to the test medicine, *Krimihar Yoga*.

## CONCLUSION

*Krimihar Yoga* provided better result in all the cardinal symptoms of the disease and on the stool examination. The present study has shown positive results on *Krimiroga* through herbal preparations. These drugs were very much effective in clearing the intestinal parasites, in addition to this; these drugs showed better action on digestion, anorexia, abdominal pain and overall improvement in general health. These drugs are

safe, not having any side or toxic effects and are natural in origin are added advantages.

## References

1. Prevalence of intestinal parasites within three population groups in Laplata, Argentina. Euro J Epidem. 1998; 14:55–61.
2. Park K, Park's Text Book of Preventive and Social Medicine, Banarsidas Bhanot, Jabalpur, India, 2000. 166.
3. Agnivesha, Charak Samhita elaborated Vidyotini Hindi commentary by Pandit Kashinath Shastri and Dr. Gorakhanath Chaturvedi, Chaukhambha Bharti Academy, Varanasi, 2006, Vimana Sthana 7/9.
4. Sushruta Samhita with Ayurveda Tattva Sandipika Hindi commentary by Kaviraj Shastri Ambikadutta, Part-II, Chaumkhambha Sanskrit Sansthan, Varanasi, 2006, Uttartantra 54/19.
5. Agnivesha, Charaka, Dridhabala, Charaka Samhita, Edited by Yadavaji Trikamaji, Fifth Edition, Chaukhambha Sanskrit Sansthana, Varanasi, 2001, *Vimanasthana Adhyaya* 7/14-15.
6. Sing Karam, Verma Bhavna, Scope of herbal Anthelmintics: An Ayurvedic Perspective, Int. J Res. Ayurveda Pharm., 2013, 4(4): 589-594.
7. The Ayurvedic Pharmacopoeia of India, Part I, Vol. I-VI, Dept. of Ayush, Govt. of India, New Delhi, Vol-I, Vidanga- 123.
8. Kwon Park II, Junheon K, Sang-Gil L. Nematicidal Activity of Plant Essential Oils and Components From Ajwain (*Trachyspermum ammi*), Allspice (*Pimenta dioica*) and Litsea (*Litsea cubeba*) Essential Oils Against Pine Wood Nematode (*Bursaphelenchus Xylophilus*) J Nematol. 2007; 39:275–9.
9. Kostyukovsky M, Rafaeli A, Gileadi C, Demchenko N, Shaaya E. Activation of octopaminergic receptors by essential oil constituents isolated from aromatic plants: Possible mode of action against insect pests. Pest Manage Sci. 2002; 58:1101–6.
10. Tamurab T, Iwamoto H. Thymol: A classical small molecule compound that has a dual effect (potentiating and inhibitory) on myosin. Biochem Biophys Res Commun. 2004; 18:786–91.
11. Jabbar A, Iqbal Z, Khan MN. *In vitro* anthelmintic activity of *Trachyspermum ammi* seeds. Pharmacogn Mag. 2006; 2:126–9.
12. Saini N *et al.* Spasmolytic potential of some medicinal plants belonging to family Umbelliferae: A Review, Int. J. Res. Ayurveda Pharm. 2014; 5(11), 74-83.
13. Bhavprakasha by Bhavmishra commentary by Dr. Chuneekar KC, edited by Dr. Pandey GS, Chaukhambha Bharti Academy, Varanasi, Haritkyadi Varga, 1/80, 28.
14. Hashmi S, Pharmacognostical standardization of Khurasani Ajwain- A Unani drug of repute. Hippocratic Journal of Unani Medicine, 1(1): 49-52.
15. Borkar VS, Gangurde HH, Gulecha VS, Bhojar PK, Mundada AS, Evaluation of in vitro antihelminthic activity of leaves of *Butea monosperma*. *International Journal of Phytomedicine* 2010; 2(1).

\*\*\*\*\*

### How to cite this article:

Swapnil Singhai and Nagesh Jaiswal.2016, An Open Labeled Randomized Study to Assess the Efficacy And Safety of Krimihar Yoga. *Int J Recent Sci Res.* 7(4), pp. 10425-10428.

T.SSN 0976-3031



9 770976 303009 >