

Clinical Research

A placebo-controlled clinical evaluation of *Kharjurapaka* in *Mamsakshaya*

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Abstract

Introduction: The world is facing most of the health problems due to nutritional imbalance, and Mamsakshaya (wasting) is one of them. Mamsakshaya explained in Kiyantahshirasiya Adhyaya can be considered as a separate entity, and it can be correlated with Karshya vyadhi. Mamsakshaya occurs due to diminished Prithvi and Jala Mahabhuta in the body and also due to improper diet and environmental factors. Kharjurapaka (KP) is having Prithvi and Jala Mahabhuta dominance and Guru (heavy), Shita (cold), Snigdha (unctuous) Guna (property) which are similar to conjugation of Mamsa Dhatu. Aim: The aim of this study is to evaluate Brimhana (nourishment) effect of KP on having signs and symptoms of Mamsakshaya patients. Materials and Methods: The study was therapeutic, interventional, randomized placebo controlled clinical trial carried out on 34 patients of Mamsakshaya. Patients were divided into two Groups. In Group A (trial group), KP (20 g) once in a day with normal water was administered for 30 days, and in Group B (control group), placebo tablet (500 mg) of roasted wheat flour for 30 days duration was administered. Effect of therapy was assessed on subjective and objective parameters, anthropometrical parameters such as body mass index (BMI), weight, and chest circumference. Results: It was found that Group A showed significant results in BMI and sign and symptom of Mamsakshaya in comparison to Group B. Conclusion: KP showed better efficacy in comparison with placebo group.

Key words: Bhrimhana, Kharjurapaka, Mamsakshaya, Karshya

Introduction

Ahara (food) is one of the tripods of life as per Ayurveda classics. [1] The transforming unit from "food" into nutrition is called as "Agni" (digestive factors), which forms the basis upon which the Ayurveda system is built. [2] According to Charaka, Mamsakshaya (wasting) persons are considered under Ashtau-ninditiya Purusha (eight despicable persons) [3] Dalhana has described Karshya as the person having lean and thin body personality, who is a patient of Mamsakshaya. [4]

According to Ayurveda classics, Rukshannapana Sevana (indulgence of dry food items), Langhana (fasting), Pramitashana (less than normal quantity of diet) or diet that aggravates Vata (dry, astringent), Atishrama (excessive exercise), Atisnana (excess bath), Ruksha Udvartana (dry powder massage), Kriyatiyoga (excessive work), Chinta (worries),

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Bhaya (fear), Shrama (excessive physical and mental activity), Shoka (grief), Vega-Nidra-Trusha-Kshudha-Nigraha (suppression of natural urges, such as sleep, thirst, and hunger), Ati Maithuna (excessive sexual intercourse), Prakriti (constitution), Beeja Dosha (heredity), Jara (old age), Vikara anushaya (continued illness), and Krodha (anger) make person lean. [5] The Mamsakshaya person does not tolerate physical exercise, hunger, thirst, disease, and drugs. [6] The lean person has Shushka-Sphika, Shushka-Udara, Shushka-Greeva (emaciation of buttocks, abdomen, and neck),

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Vyayamam Atisauhityam (intolerance of physical exercise), Dhamanijal Santataha (prominent vascular network) Twagasthi shosha (remnant of skin and bone), Kshutpipasamay (suffering from hunger and thirst), Sthoolaparva (thick nodes), Atishitoshna-Maithunasahatva (cannot tolerate much cold, heat, and sexual intercourse).^[7]

Mamsakshaya is Vata dominant disease. Treatments such as Bhrimhana and Rasayana have been advocated in the classics for its management. The selected drug Kharjura is described in Bhavaprakasha. [8] It has the property of Vatanulomana [9] and Bhrimhana. [10] The present study is aimed to evaluate the effect of Kharjurapaka (KP) on Mamsakshaya (lean) patients.

Materials and Methods

Patients having the clinical features of "Mamsakshaya" such as Shushka-Sphika, Shushka-Udara, Shushka-Greeva (emaciation of buttocks, abdomen, and neck), Dhamani Jala Santataha (visible web of veins) Twagasthi shosha (remnant of skin and bone), Sthoolaparva (thick nodes), Glani (giddiness), and Alpa Nidra (inadequate sleep) attending the out patient department and inpatient department of the hospital were selected irrespective of caste, religion, occupation, and sex. The present clinical trial has been carried out after obtaining approval from Institutional Ethics Committee (No.: PGT/7-A/ Ethics/2013-14/1767, Dated: September 10, 2013). The trial was registered in Clinical Trial Registry-India (CTRI/2015/07/006021, Dated: July 16, 2015). Written informed consent has been taken from all the patients before starting the trial. The study was designed as open-label, randomized placebo controlled clinical trial.

Inclusion criteria

- Patients between 16 and 50 year age group without any bar of race, religion, and sex
- Patients having low body weight (15–20% below than normal for their age and height) and lower body mass index (BMI) (under 18.5) with clinical features of Mamsa Dhatu Kshaya
- Patients having proper Agnibala (digestive power) were selected.

Exclusion criteria

Patients having any systemic disease or history of chronic diseases such as tuberculosis, cancer, and autoimmune diseases which cause weight loss.

Grouping and posology

A total of 34 patients were registered for the present study, and coin toss method was adopted for randomization of patients. Patients were divided into two groups:

- Group A (treatment group): KP 20 g once in a day with normal water was administered for 30 days
- Group B (control group): Placebo tablet (500 mg) of roasted wheat flour was administered once in a day with normal water for 30 days.

Preparation method of Kharjurapaka

KP was prepared in the Department of Rasa Shastra and Bhaishajya Kalpana by following classical method of Paka

preparation. [11] Kharjura (Phoenix dactylifera Linn.) was collected and its seeds were taken out. Kharjura pulp was made in to small pieces. Then, Kharjura and cow ghee were taken in the ratio of 10:1 and it was fried on mild temperature for 10–12 min and was stirred continuously so that it would not get scorched. As the fibril consistency was observed, then frying process was stopped and the process of preparation of Paka (in the form of Modaka) was done. Kharjura was procured from local market.

Investigations

Routine pathological tests such as (hemoglobin %, erythrocyte sedimentation rate, random blood sugar), urine (routine microscopic and macroscopic), stool (routine microscopic and macroscopic), and biochemical investigation (serum cholesterol, serum triglyceride, fasting blood sugar, high-density lipoprotein cholesterol, serum low-density lipoprotein, total protein, serum albumin to globulins ratio) were carried out to rule out any pathology before treatment.

Criteria for assessment of therapy

Subjective parameter

It has been mainly assessed on improvement in cardinal signs and symptoms of disease with the help of scoring pattern such as follows:

- 1. Aayasa (lassitude)
 - 0: No Aayasa
 - 1: Little Aayasa in doing hard work
 - 2: Moderate Aayasa in doing hard work
 - 3: Excessive Aayasa in doing routine work.
- 2. Glani (giddiness)
 - 0: No Glani at the level of physique, senses, and psyche
 - 1: Feel Glani at any level of physique but not appear on the face
 - 2: Little *Glani* at any level of physique, senses, and psyche
 - 3: Excessive *Glani* at any level of physique, senses, and psyche.
- 3. Dhamani Jala Darshana (prominent vasculature)
 - 0: Not visible easily even after pressure
 - 1: Visible and prominent on pressure
 - 2: Visible
 - 3: Prominent.
- 4. Sthula Parva (knee, elbow, ankle, wrist joint)
 - 0: Deeply seated with extra fat
 - 1: Covered
 - 2: Prominent
 - Relatively look larger.
- 5. Kapola Gata Vasa (pad of fat on cheek)
 - 0: Cheeks everted
 - 1: On surface level
 - 2: Cheeks inside
 - 3: Cheeks inside with zygomatic bones prominent.
- 6. Daurbalya (fatigue)
 - 0: Not feeling Daurbalya in doing any hard work
 - 1: Not feeling Daurbalya in doing easy work
 - 2: Feeling Daurbalya in doing little work
 - 3: Feel Daurbalya in rest position.

Table 1: Effect of Kharjurapaka on Lakshanas of Mamsakshaya in Group A

Lakshanas	n	Percentage relief	Mean		SD	SE	t	P
			ВТ	AT				
Aayasa	14	65.39	1.85	0.64	0.57	0.15	7.84	<0.001
Glani	15	76	1.66	0.4	0.59	0.15	8.26	< 0.001
Dhamani Jala Darshana	15	29.03	2.06	1.46	0.21	0.21	2.86	0.01
Kapolgatavasa	15	18.18	1.46	1.2	0.11	2.25	2.25	0.02
Sthula Parva	15	22.72	1.46	1.13	0.12	0.12	2.64	0.01
Daurbalya	15	57.70	1.73	0.73	0.09	0.09	10.24	< 0.001
Shoka	15	70	2	0.6	10.63	1.13	10.69	< 0.001
Nidra	14	80	1.42	0.28	0.09	0.09	11.77	< 0.001

BT: Before treatment, AT: After treatment, SD: Standard deviation, SE: Standard error

Table 2: Effect of placebo tab on Lakshanas of Mamsakshaya in Group B

Lakshanas	n	Percentage	Me	ean	SD	SE	t	P
		relief	ВТ	AT				
Aayasa	15	53.57	1.86	0.86	0.37	0.09	10.24	<0.001
Glani	15	55.56	1.2	0.53	0.72	0.18	3.56	0.01
Dhamani Jala Darshana	15	32	1.66	1.13	0.63	0.16	3.22	0.01
Kapolgatavasa	15	36	3.87	3.87	0.63	0.16	3.67	0.01
Sthula Parva	15	25	1.86	1.4	0.51	0.13	3.5	0.01
Daurbalya	15	69.23	3.87	3.87	0.42	0.10	11.22	< 0.001
Shoka	15	48	3.87	3.87	0.41	0.10	7.48	< 0.001
Nidra	9	72.72	3	3	0.33	0.11	8	< 0.001

BT: Before treatment, AT: After treatment, SD: Standard deviation, SE: Standard error

Table 3: Effect of *Kharjurapaka* on weight, fat%, and body mass index in Group A (*n*=15)

Parameter Percentage		Me	Mean		SE	t	P
	Change	BT	AT				
Weight	2.56	42.22	43.34	0.67	0.17	6.36	<0.001
BMI	3.96	16.45	17.13	0.44	0.11	5.94	< 0.001
Fat%	3.62	16.31	16.92	0.50	0.12	4.73	<0.001

BT: Before treatment, AT: After treatment, SD: Standard deviation, SE: Standard error, BMI: Body mass index

7. Shoka (grief)

- 0: No sorrow even for reasonable cause
- 1: Sorrowful only for reasonable cause
- 2: Sorrowful even nonreasonable cause without anybody gesture
- 3: Most sorrowful for no cause, unable to control his feelings, body gestures.

8. Nidra (sleep)

- 0: 6–8 h deep sleep
- 1: 6-8 h sleep but disturbed once
- 2: <6 h sleep but disturbed twice
- 3: <6 h sleep but disturbed frequently.

Objective parameter

Anthropometrical parameters such as BMI, weight, chest circumference, mid-arm circumference, and also skin fold thickness – biceps, triceps, and abdomen.

Statistical analysis

The statistical tests such as paired and unpaired t-test were applied for significance. Computer software SigmaStat (Systat Software, San Jose, California) was used for the calculation of statistical data.

Observation

A total of 34 patients (17 in Group A and 17 in Group B) were registered in the trial, and out of which, 30 completed (15 in each group) the treatment. Age-wise distribution shows that 52.9% of the patients were between 16 and 25 years, 32.4% were in the age of 26-35 years, 14.7% were 36-50 years of age group. Majority of the patients, i.e., 67.6% were female while 32.4% were male. Maximum, i.e., 71% patients were taking vegetarian diet whereas 29% patients were taking mixed type of diet. The present study shows that maximum 76% patients were taking Katu Rasa Pradhana (pungent-dominant taste) diet whereas 74% patients had dominance of Lavana Rasa in their diet. Maximum 59% patients were taking Ruksha Guṇa Pradhana (dry-dominant property) diet whereas 47% patients were taking Ushna Guna Pradhana (hot-dominant property) diet and 44% patients were taking Sheeta Guna Pradhana (cold dominant property) diet. 41.18% patients had a habit of Divaswapa (daytime sleep) while 47.06% patients had a history of Ratrijagarana (late night sleep). Maximum, 58.83% patients, had the habit of Kshudha Vega Vidharana (suppression of

hunger) whereas in 38.24% of the patients had a history of *Trishna Vega Vidharana* (suppression of thirst).

Results

Effect of therapy on chief complaints

Group A depicted highly significant (\dot{P} < 0.001) results in

Table 4: Effects of placebo tablet on weight, fat%, body mass index in Group B (*n*=15)

Parameter	eter Percentage		Mean		SE	t	P
	Change	BT	ΑT				
Weight	1.75	43.38	44.04	0.19	0.73	4.02	<0.001
BMI	1.85	15.96	16.26	0.07	0.27	4.27	0.001
Fat%	3.51	18.7	19.38	0.28	1.09	2.41	0.02

BT: Before treatment, AT: After treatment, SD: Standard deviation, SE: Standard error, BMI: Body mass index

Aayasa, Glani, Daurbalya, Shoka, and Nidra and significant (P < 0.05) results in Dhamani Jala Darshana, Kapolgatavasa, and Sthula Parva [Table 1]. In Group B, highly significant (P < 0.001) effects on Aayasa, Daurbalya, Shoka, and Nidra and insignificant results depicted in Glani, Dhamani Jala Darshana, Kapolgatavasa, and Sthula Parva [Table 2].

Effect of therapy on anthropometrical parameter and skin fold thickness

KP in Group A rendered highly significant (P < 0.001) results in reducing value of BMI, fat%, and weight, and placebo tablet in Group B rendered highly significant (P < 0.001) decrease in weight and insignificant change in BMI and fat% [Tables 3 and 4].

Group A depicted significant (<0.01) results in reducing value in millimeter in chest circumference, forearm circumference, mid-arm circumference, mid-thigh circumference and insignificant result in mid-calf circumference [Table 5].

Table 5: Effect of Kharjurapaka on anthropometrical parameter and skin fold thickness in Group A (n=15)

Parameter	Percentage	Me	Mean		SE	t	Р
	relief	ВТ	AT				
Chest circumference	0.42	69.04	69.34	0.36	0.09	3.12	0.01
Fore arm circumference	1.56	18.90	19.20	0.31	0.08	3.67	0.01
Mid-arm circumference	1.44	21.4	21.71	0.31	0.08	3.86	0.01
Mid-thigh circumference	0.97	36.5	36.86	0.39	0.10	3.50	0.01
Mid-calf circumference	2.38	30.5	31.24	1.77	0.45	1.64	0.10
Skin fold thickness of biceps	8.17	1.94	2.12	0.23	0.06	2.86	0.02
Skin fold thickness of triceps	9.56	2.82	3.12	0.40	0.10	2.87	0.02
Skin fold thickness of abdomen	6.23	1.6	1.70	0.12	0.03	3.37	0.01

BT: Before treatment, AT: After treatment, SD: Standard deviation, SE: Standard error

Table 6: Effects of placebo tablet on anthropometrical parameters and skin fold thickness in Group B (n=15)

Parameter	Percentage relief	Me	Mean		SE	t	Р
	· ·	ВТ	AT				
Chest circumference	0.60	77.1	77.56	0.13	0.52	3.44	0.01
Fore arm circumference	1.40	18.26	18.52	0.08	0.33	3.03	0.01
Mid-arm circumference	1.43	21.06	21.37	0.08	0.33	3.51	0.01
Mid-thigh circumference	0.72	37.6	37.87	0.08	0.33	3.16	0.01
Mid-calf circumference	1.04	27.9	28.19	0.08	0.31	3.66	0.01
Skin fold thickness of biceps	6.62	1.88	2.01	0.04	0.17	3.00	0.01
Skin fold thickness of triceps	4.45	2	2.09	0.02	0.07	4.52	< 0.001
Skin fold thickness of abdomen	9.90	1.33	1.48	0.03	0.13	4.36	< 0.001

 $BT: Before\ treatment, AT: After\ treatment, SD: Standard\ deviation, SE: Standard\ error and an experiment of the standard deviation of the stand$

Table 7: Comparative efficacy of treated Group A with control Group B on Lakshanas of Mamsakshaya

Lakshanas	df	Mean (perce	entage relief)	SD	t	P
		Group A	Group B			
Aayasa	27	65.39	53.57	58.26	0.911	0.10
Glani	28	76	55.56	8.17	2.244	0.02
Dhamani Jala Darshana	28	29.03	32	40.28	0.332	0.10
Kapolgatavasa	28	18.18	36	30.87	1.372	0.10
Shula Parva	28	22.72	25	8.17	0.316	0.10
Daurbalya	28	57.70	69.23	29.69	0.984	0.10
Shoka	28	70	48	25.10	1.543	0.10
Nidra	21	80	72.72	23.45	0.640	0.10

SD: Standard deviation

Group B rendered significant (<0.01) results in reducing value in millimeter in chest circumference, forearm circumference, mid-arm circumference, mid-thigh circumference, and mid-calf circumference [Table 6]. Group A depicted significant results in reducing value in millimeter in all the skin fold thickness (biceps, triceps, abdomen) and highly significant (<0.001) result in skin fold thickness of triceps and abdomen and significant result in reducing value in millimeter in skin fold thickness of biceps in Group B [Tables 5 and 6].

Comparative efficacy of therapy

In *Glani* and fat%, Group A had provided better results than Group B [Table 7]. The observations on contingency table were not significantly related as P value in comparative groups Group A and Group B (P > 0.05). This suggested that change occurred with the treatments was not enough to exclude the possibility that the difference was due to chance. Hence, both the groups have parallel effect on symptom of *Mamsakshaya* score of disease according to statistical analysis [Tables 8 and 9].

Discussion

Mamsa Dhatu Kshaya causes the increase of Vayu and Aakash Mahabhuta; consequently, this causes increase of Vata Dosha which is composed of these Mahabhutas. [12] Charaka has quoted that naming all types of diseases in definite terms is not possible, when aggravated the same Dosha may cause manifold diseases depending upon the various etiological factors and the sites of manifestation. [13] Hence, Mamsakshaya is taken as symptom and treated with KP. Similarly, in Mamsakshaya, there is a predominance of Vata Dosha which can be alleviated by the treatment of Brimhaniya Dravyas composed of Prithvi and Jala Mahabhuta. Ahara Dosha is

Table 8: Comparative efficacy of treated Group A with control Group B on weight, fat%, and body mass index

Parameters	df	Mean (percei	SD	t	P	
		Group A	Group B			
Weight	30	2.56	1.75	0.16	1.57	0.10
BMI	28	3.96	1.85	0.11	0.21	0.10
Fat%	28	3.62	3.51	0.12	2.83	0.01

BMI: Body mass index, SD: Standard deviation

the main predisposing factor for this disease and Alpashana and Vishamashana (improper diet) specially results in the advancement of Mamsakshaya. Pharmacotherapies such as Bhrimhana, Rasayana, and Vrishya have been advocated in the classics for the patients of Mamsakshaya. Madhura Rasa, Snigdha, Guru, Sthira Guna, Sheeta Virya of drugs gives relief to vitiated Vata Dosha. The ultimate aim of treating Mamsakshaya is to achieve a proportionate body. Probable mode of action of Bhrimhana Dravyas can be accessed on the ground of its property. It is found that the ingredient has predominance of Guru, Snigdha, Shita, and Manda Guna; Madhura Rasa and Madhura Vipaka lead to Vatanulomana and act as Bhrimhana.

Nutritional analysis of KP shows the presence of macronutrients such as energy (352.2 kcal), sugar (57.3 g), carbohydrate (77.6%w/w), protein (4.4%w/w), and fat $(2.8\%\text{w/w})^{[14]}$ for each 100 g sample. Major source of energy is macronutrients which are needed for growth, metabolism, and other body metabolism. The present result indicates the potentiality of KP as unconventional food. Kharjura is easily accessible and cheaper source of good nutrition. Vitamins C, Vitamins B, thiamine, B, riboflavin, nicotinic acid (niacin), and Vitamin A are present in Kharjura. Fourteen varieties of dates have been shown to be as high dietary fiber of 6.4-11.5%, [15] which depending on variety and degree of ripeness. Kharjura contains 0.5-3.9% pectin, which has valuable health benefits. These are attributed to the rich contents of antioxidant in date fruit such as ferulic acid and coumaric acid. Moreover, it contains procyanidins, flavonoids, sterols, sugar (glucose, sucrose, and fructose) carotenoids, anthocyanins, dietary fibers, thiamine, ascorbic, folic acid, and minerals such as cobalt magnesium, fluorine, manganese, calcium, iron, copper, phosphorus, boron, sulfur, zinc potassium, sodium, and selenium within the date palm itself.[16] Hence, Kharjura acts as a good nutritive fruit and also when it made with ghee, then the potency of drug increases.

Probable mode of action of Kharjurapaka

KP having a property of Madhura Rasa (sweet in taste) and Madhura Vipaka has diminished the Vata Dosha. Vatanulomana property of formulation helps in balance and maintenance of Agni and ultimately causes proper digestion of food. Guru, Shita, Snigdha, and Mrudu Gunas (soft property) are directly responsible for Bhrimhana effect.

Table 9: Comparative efficacy of treated Group A with Control Group B on anthropometrical parameter and skin fold thickness

Parameters	df	Mean (perce	ntage relief)	SD	t	P
		Group A	Group B			
Chest circumference	28	0.42	0.60	0.09	1.05	0.10
Fore arm circumference	28	1.56	1.40	0.08	0.33	0.10
Mid-arm circumference	28	1.44	1.43	0.08	0.05	0.10
Mid-thigh circumference	28	0.97	0.72	0.10	0.64	0.10
Mid-calf circumference	28	2.38	1.04	0.45	0.97	0.10
Skin fold thickness of biceps	28	8.17	6.62	0.06	0.53	0.10
Skin fold thickness of triceps	28	9.56	4.45	0.10	1.94	0.10
Skin fold thickness of abdomen	28	6.23	9.90	0.03	0.86	0.10

SD: Standard deviation

KP having *Prithvi* and *Jala Mahabhuta* dominance is somewhat equivalent to property of *Mamsa Dhatu*; further, the available nutritive data of *KP* show it a competitive source of nutrition so it helps for nourishment of *Mamsa Dhatu* in better way. The *Kharjura* has maximum essential macronutrients and micronutrients. The prepared KP with ghee is a very well accepted for its palatability and taste.

Conclusion

The present clinical study shows that the selected drug KP helps to improve the sign and symptoms of *Mamsakshaya*. KP showed marginal better in comparison with placebo control group. KP is useful for the treatment of *Mamsakshaya*.

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Conflicts of interest

There are no conflicts of interest.

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हिन्दी सारांश

प्लासिबो कन्ट्रोल का खर्जूर पाक के साथ मांसक्षय पर चिकित्सकीय विश्लेषण

सुजाता धोके, रामबाबू द्विवेदी, महेश व्यास

आयुर्वेद चिकित्सा प्रणाली में बृंहण कर्म एक विशेष चिकित्सा है। इस शोध कार्य में मांसक्षय व्याधि से पीड़ित रूग्ण में खर्जूर पाक इस योग का आभ्यान्तर प्रयोग बृंहण चिकित्सा हेतु किया गया है। वायु और आकाश महाभूत की प्रतिकारक निदानों से शरीर में वात दोष वृद्धि होकर शरीर में मांस धातु का क्षय होते हुये दिखाता है, तदर्थ पृथ्वी और जल महाभूत प्रधान द्रव्य खर्जूर पाक द्वारा चिकित्सा प्रयोग किया गया है। शोध कार्यार्थ ३४ रूग्णों को यादृच्छिक पद्धित द्वारा दो वर्गों में चयन किया गया। प्रथम वर्ग 'अ' में कुल १७ रूग्ण और दूसरे वर्ग 'ब' में १७ रूग्ण का पंजीकरण किया गया। जिनमें से क्रमशः १५-१५ रूग्णों ने दोनों वर्गों में अंत तक चिकित्सा ली। प्रथम वर्ग के रूग्णों को खर्जूर पाक प्रतिदिन २० ग्रा. प्रातः निरन्नकाल में जल के साथ दिया गया एवं द्वितीय वर्ग के रुग्णों को केवल प्लासिबो टेबलेट प्रतिदिन ५०० मिलिग्राम (२ टेबलेट) प्रातः निरन्नकाल में जल के साथ दिया गया। चिकित्सा के अंत में सांख्यिकीय दृष्टि से औषध के प्रभाव का परिगणन करते हुए यह पाया गया कि मांसक्षय के लक्षणों में प्रथम वर्गों के रुग्णों को आशातित उत्तम परिणाम मिले जब की द्वितीय वर्गों में कुछ मापदण्ड पर सार्थ परिणाम प्राप्त हुए।