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Original Article
Clinical trial

Impact of Mercury on the Efficacy of *Amavatari Rasa* in Rheumatoid Arthritis: A Randomized Double Blind Trial

Sonam S Bhinde,[1*] Galib R,[2] Pradeep K Prajapati[3]

[1]Lecturer, Manjushri Research Institute of Ayurvedic Sciences, Gandhi Nagar, Gujarat. [2]Associate Professor, [3]Professor and Head, Department of Rasa Shastra and Bhaishajya Kalpana, All India Institute of Ayurveda, New Delhi, INDIA 110076.

Correspondence: Email: sonamduvani@gmail.com, Mobile: +91-9558788818

ABSTRACT

Introduction: Rheumatoid arthritis (RA) is one of the most challenging diseases due to its chronicity, incurability, complications and morbidity. It is an auto-immune inflammatory disease. From Ayurveda point of view, this disease can be correlated with *Amavata* in its clinical presentation. In spite of potent anti-inflammatory and powerful immunosuppressive agents; itsprognosis is bad and these drugs are associated with certain side effects too. Ayurveda holds various formulations for this condition and *Amavatari Rasa,* a mercurial formulation is one among them. Aim of the current study is to evaluate impact of Mercury on the efficacy of *Amavatari Rasa* in Rheumatoid Arthritis through double blind trial. ***Methods:*** Total 86 patients were registered and randomly divided into two groups and were treated with *Amavatari Rasa* prepared in absence of mercury (ARM) and *Amavatari Rasa* with mercury (ARC) at dose of 250 mg thrice a day, 30 minutes before meal with luke warm water for 8 weeks. Assessment was done on the basis of clinical recovery, symptomatic relief and pathological investigations. ***Results:*** At the end of the trial; the nature of the trial drugs was unveiled.Both the formulations showed highly significant results ($p<0.001$) in all the signs and symptoms except *trishna* (thirst). Majority of the signs and symptoms were better relieved with ARM group, whereas biological markers corrected with ARC group. Though, there is no significant difference in between the results of both the groups, ARC appears to be influencing the cellular level of pathology, while ARM is helpful in providing symptomatic relief. ***Conclusion:*** Thus, it can be inferred that, presence of mercury is essential that helps in taking the drug to the cellular levels and breaking the pathology successfully. No untoward effects were noticed in any patients during the study period.

KEYWORDS

Amavata, *Amavatari Rasa*, Mercury, Rheumatoid Arthritis.

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*A*mavata is described as a difficult to cure (*Krichhrasadhya*) disease in Ayurveda. Pain in joints with swelling is a cardinal feature of this disease. It can be correlated with rheumatoid arthritis described in modern medical science. It is an auto-immune inflammatory disease. In spite of potent anti-inflammatory and powerful immunosuppressive agents; its prognosis is bad. These drugs are also known to develop side effects as well. Ayurvedic system of medicine with a number of herbal and herbo-mineral formulations has good hope for this condition. *Amavatari Ras a*is one of the familiar medicaments used throughout India by Ayurvedic physicians for *Amavata*.[1] It is a herbo-mineral formulation containing *Parada* (Mercury), *Gandhaka* (Sulphur), *Triphala* (three myrobalans), *Chitraka* (*Plumbagozeylanica* Linn.), *Guggulu* (*Commiphora wightii* (Arn.) Bhandari and *Eranda taila* (oil of *Ricinus communis* Linn.). Mercury is being used since long without any noticeable side effectsortoxicity in variouys forms. As the contemporary scientists are raising concerns on mercury in therapeutics; it becomes essential to evaluate its usefulness in therapeutics and generate safety data on mercurial preparations in presence and absence of mercury. Considering this, it is planned to evaluate impact of Mercury on the efficacy of *Amavatari Rasa* with or without mercury in Rheumatoid Arthritis through double blind trial.

MATERIALS AND METHODS

Preparation of trial drug

First, purification of *Hingula, Gandhaka* and *Guggulu* were done by following classical guidelines. Then *Parada* procured from *Hingula* by *Nada Yantra* method. *Kajjali* was prepared and it was taken in *Khalva Yantra* and *Mardana* was done for 10 minutes. *Triphala Churna* and *Chitraka Churna*were added one after the other in *Kajjali* and triturated till a homogenous mixture was achieved. Then *Shuddha Guggulu* was powdered and added to *Kajjali* and *Mardana* was done till complete mixing of *Guggulu* with *Kajjali* was achieved and a uniform blend is obtained. *Eranda taila* was mixed in above mixture and triturated till a soft, smooth, homogenous mixture to obtain *Amavatari Rasa* (ARC) that was filled in capsules. Same method was followed in the preparation of *Amavatari Rasa*, avoiding mercury from the composition (ARM).

Source of data

Patients attending the OPD and IPD of *Rasashastra* and *Bhaishajya Kalpana*, IPGT & RA, GAU, Jamnagar and fulfilling inclusion criteria were selected for this study. The study obtained clearance from Institutional Ethics Committee (No.PGT/7/-A/Ethics/2014-15/1538) and registered at Clinical Trial Registry India retrospectively through CTRI/2015/10/006309.

Inclusion criteria

Patients of both sex, between 20 to 50 years of age with classical symptoms of *Amavata*[2] i.e. *Angamarda* (Body ache), *Aruchi* (Anorexia), *Trishna* (Thirst), *Alasya* (Laziness), *Gauravam* (Heaviness), *Jvara* (Fever), *Apaka* (Indigestion), *Shoonata Anganam* (Numbness of involved parts of body). Patients who had satisfied the criteria laid down by the American Rheumatism Association (ARA)[3]were selected and registered for detailed investigation and follow-up. The ARA criteria are morning stiffness lasting for more than one hour, arthritis of three or more joints, arthritis of hand joints, symmetrical arthritis, presence of rheumatoid nodules, presence of rheumatoid factor, typical radiographic changes of arthritis on PA view of hand and wrist radiograph that must include erosions and unequivocal decalcification adjacent to involve joints. The first four ARA criteria must be present for the duration of six weeks or more and the other three criteria were kept as optional for the selection of patients.

Exclusion criteria

Patients having chronic complications like severe crippling deformities and other forms of arthritis like ankylosing spondylosis, osteo-arthritis etc. and patients who had a positive history of diabetes mellitus, pulmonary tuberculosis, hypertension, cardiac disease, liver disease were also excluded from the study.

Criteria for withdrawal

Any serious complications developed that require immediate intervention were withdrawn from the study.

Investigations

Rheumatoid Factor {RA factor (quantitative)}, routine pathological and haematological (TC, DC, Hb, ESR), urine-routine and microscopic and biochemical parameters like LFT, RFTCRP test (c-reactive protein test) were done in all enrolled patients.

Grouping and posology

Selected patients were randomly grouped into two by computer generated randomization sequence. The trial drugs were encapsulated, double blinded and administered to respective groups at a dose of 250 mg thrice a day[4] 30 minutes before meal, with luke warm water as adjuvant for eight weeks. Follow up period was 14 days in both groups.

Statistical tools

Wilcoxon test for subjective criteria, Paired - t for objective criteria and unpaired -t for comparison in between the groups were adopted.

Scoring pattern

The following was adopted for gradation of symptoms and overall effect of therapy.[5]

Symptom	Grade
Sandhishoola **(Severity of Pain)**	
No pain	0
Mild pain	1
Moderate, but no difficulty in moving	2
Slight difficulty in moving due to pain	3
Much difficulty in moving the bodily parts	4
Severity of swelling	
No swelling	0
Slight swelling	1
Moderate swelling	2
Severe swelling	3
Sandhigraha **(Stiffness)**	
No stiffness	0
5 min to 2 hours	1
2 hours to 8 hours	2
More than 8 hours	3
Sparshasahatva **(Tenderness)**	
No tenderness	0
Subjective experience of tenderness	1
Wincing of face on pressure	2
Wincing of face and withdrawal of the affected part on pressure	3
Resist to touch	4
Angamarda **(Body ache)**	
No Body ache	0
Mild Body ache	1

Moderate Body ache	2
Severe Body ache	3
***Aruchi* (Tastelessness)**	
No *Aruchi*	0
Willing towards some specific food	1
Willing towards only most liking food and not to other foods	2
Totally unwilling for food	3
***Trishana* (Polydypsia)**	
No *Trishna*	0
Occasional *Trishna*	1
Very often *Trishna*	2
Always feeling of *Trishna*	3
***Aalasya* (Malaise)**	
No*Alasya*	0
Doing work satisfactorily with late initiation	1
Doing work unsatisfactorily under mental pressure and takes time	2
Not starting any work on his own responsibility and doing little work very slowly	3
Does not take any initiation and does not want to work even after pressure	4
***Gaurava* (feeling of heaviness)**	
No heaviness in the body	0
Feels heaviness in the body but it does not hamper routine work	1
Feels heaviness in the body which hampers daily routine work	2
Feels heaviness in the body which hampers movement of the body	3
Feels heaviness in the body along with flabbiness which causes great distress to the person	4
***Apaka* (Indigestion)**	
No *Apaka*	0
Occasionally indigestion related to heavy food	1
Apaka occurs daily after each meals and takes 4 to 6 hours for *UdgaraShuddhi*…etc symptoms	2
Apaka occurs daily after each meal,do not have hunger	3
Never gets hungry always heaviness in abdomen. Followed by vomiting…etc, symptoms	4
***Jwara* (Fever)**	
No fever	0
Occasional fever subsides by itself	1
Occasional fever subsides by drug	2
Remittent fever	3
Continuous fever	4
***Shoonata-anganam* (numbness)**	
No numbness	0
Mild numbness occasionally	1
Numbness on sitting and in some parts of the body	2
Severe numbness	3

RESULTS AND DISCUSSION

The results obtained during clinical study in the signs and symptoms of the registered patients were assessed and analyzed statistically before and after treatment. The nature of drugs was unveiled at the end of the treatment period and it was revealed that patients of Group-A received *Amavatari Rasa* prepared in absence of mercury (ARM), while Group-B received *Amavatari Rasa* prepared by following classical guidelines (ARC) that is in presence of mercury.

With the intervention of ARM; highly significant decrease ($p<0.001$) was found in all cardinal symptoms (Table1) i.e. *Angamarda, Aruchi, Alasya, Gaurava,Apaka* and *Jwara*, whereas *Shoonangata* showed significant relief ($p=0.031$). Relief in *Trishna (p=0.031)* was statistically insignificant (Table1). Statistically insignificant results on RA ($p=0.898$), CRP ($p=0.765$) and ESR ($p=0.525$)were observed (Table2).

Table 1. Effect on ARM on cardinal &classical symptoms

Group A(ARM)	N	Mean Score		Difference ± SEM	% change	W	P
		BT	AT				
SandhiShoola (Joint Pain)	40	2.62	1.4	1.22↓±0.08	46.56	741	<0.001**
SandhiShotha (edema)	38	2.00	0.57	1.43↓±0.129	71.50	666	<0.001**
Sandhi Graha (Morning Stiffness)	37	1.89	0.94	0.95↓±0.122	50.26	378	<0.001**
Sparshasahatva (Tenderness)	35	1.91	0.80	1.11↓±0.105	58.11	496	<0.001**
Angamarda (Body ache)	40	2.30	1.12	1.18↓±0.10	51.30	666	< 0.001**

Aruchi (Tastelessness)	35	1.68	0.60	1.08↓±0.10	64.28	465	< 0.001**
Trishna (Polydypsia)	6	1.16	0.16	1↓±0.00	86.20	21	0.031#
Aalasya (Malaise)	33	2.00	0.81	1.19↓±0.13	59.50	465	< 0.001**
Gaurava (feeling of heaviness)	34	2.26	1.02	1.24↓±0.114	54.86	496	< 0.001**
Apaka (Indigestion)	25	1.68	0.56	1.12↓±0.08	66.66	300	< 0.001**
Jwara (Fever)	23	1.82	0.69	1.13↓±0.18	62	210	< 0.001**
Shuoonata-anganam (Numbness)	13	1.53	0.84	0.69↓±0.26	45.09	21	0.031*

Data: Mean ± SEM, ↓Decrease * significant ** highly significant #insignificant

Table 2. Effect of ARM on RA Factor and CRP

Group A (ARM)	N	Mean Score ± SEM		% change	Difference ± SEM	T	P
		BT	AT				
RA	40	95.14±29.00	92.03±29.92	3.27	3.11↓±24.01	0.130	0.898#
CRP	35	6.211±2.029	6.541±1.681	5.29	0.329↑±1.095	0.301	0.765#
ESR	40	31.94	34.30	7.39	2.36↑±3.67	0.642	0.525#

Data: Mean ± SEM, ↓Decrease, #insignificant

ARC showed highly significant decrease in all cardinal symptoms and other symptoms except *Jwara* and *Shoonangata* that were significant (Table 3).

Table 3. Effect on ARC on Cardinal and classical symptoms

Group B (ARC)	N	Mean Score		Difference ± SEM	% change	W	P
		BT	AT				
SandhiShoola(Joint Pain)	40	2.7	1.32	1.38 ↓±0.09	51.11	741	<0.001**
SandhiShotha (edema)	35	2.06	0.77	1.29↓±0.08	62.62	595	<0.001**
Sandhigraha (Morning Stiffness)	38	1.97	1	0.97↓±0.11	49.24	435	<0.001**
Sparshasahatva (Tenderness)	33	1.94	1.09	0.85↓±0.10	43.81	300	<0.001**
Angamarda (Body ache)	40	2.02	0.95	1.07↓±0.06	52.97	741	<0.001**
Aruchi(Tastelessness)	25	1.72	0.52	1.2↓±0.11	69.77	276	<0.001**
Trishana(Polydypsia)	5	1	0.6	0.4↓±0.24	40	3	0.346#
Aalasya (Malaise)	33	2.03	0.97	1.06↓±0.10	52.22	406	<0.001**
Gaurava(feeling of heaviness)	30	2.37	1.27	1.10↓±0.08	46.41	406	<0.001**
Apaka(Indigestion)	18	2.11	0.94	1.17↓±0.14	55.45	136	<0.001**
Jwara(Fever)	17	1.70	0.76	0.94↓±0.20	55.29	55	0.005*
Shunata-anganam(numbness)	15	1.87	1	0.87↓±0.165	46.52	55	0.004*

Data: Mean ± SEM, ↓Decrease * significant ** highly significant #insignificant

Relief in *Trishna (p=0.346)* was also statistically insignificant (Table 3) in this group. Changes in RA Factor, CRP and ESR were statistically insignificant but still they were decreased by 16.18%, 28.34% and 13.88% respectively suggesting the reduction in inflammatory process (Table4).

Table 4. Effect of ARC on RA Factor and CRP

Group B (ARC)	N	Mean Score ± SEM		% change	Difference ± SEM	T	P
		BT	AT				
RA	40	61.13±9.01	51.23±12.90	16.18	9.89↓±13.39	0.739	0.464#
CRP	27	12.84±3.83	9.20±2.89	28.34	3.64 ↓±2.39	1.520	0.141#
ESR	40	32.07	27.62	13.88	4.45↓±3.00	1.48	0.146#

Data: Mean ± SEM, ↓Decrease, #insignificant

In comparative effect of therapy; data shows statistical insignificant difference between both the groups on cardinal and classical symptoms (Table5).

Table 5. Comparative effect of therapy on cardinal and classical symptoms

Parameters	Group A		Group B		P
	N	Mean diff ± SEM	*N*	Mean± SEM	
Joint Pain	40	1.23↓±0.083	40	1.38↓±0.11	0.269#

Edema	38	1.42↓±0.13	35	1.28↓±0.09	0.395#
Morning Stiffness	37	0.97↓±0.12	38	0.97↓±0.12	0.993#
Tenderness	35	1.11↓±0.11	33	1.03↓±0.12	0.883#
Angamarda	40	1.18↓±0.10	40	1.07↓±0.06	0.408#
Aruchi	35	1.08↓±0.10	25	1.02↓±0.11	0.468#
Trishana	6	1.00↓±0.00	5	0.40↓±0.24	0.024#
Alasya	33	1.19 ↓±0.10	33	1.06↓±0.10	0.412#
Gaurav	34	1.24↓±0.11	30	1.10↓±0.08	0.266#
Apaka	25	1.12↓±0.08	18	1.17↓±0.15	0.774#
Angasunnata	13	0.69↓±0.26	15	0.87↓±0.17	0.579#
Jwara	23	1.13↓±0.09	17	0.94↓±0.21	0.018#

Data: Mean ± SEM, ↓Decrease, #insignificant

The change in grip power and foot pressure in between the groups was also statistically insignificant (Table6).

Table 6. Comparative effect of therapy on Grip power and Foot Pressure

	Group A		Group B		P
	N	Mean± SEM	N	Mean± SEM	
Grip power	40	2.850↑±0.409	40	3.275↑±0.813	0.642#
Foot pressure	40	2.10↑±0.299	40	2.50↑±0.305	0.304#

Data: Mean ± SEM↑ increase, ↓Decrease, #insignificant

Statistically insignificant changes in RA Factor, CRP and ESR were observed in between the groups (Table7).

Table 7.Comparative effect of therapy on RA factor, CRP& ESR

	Group A		Group B		P
	N	Mean± SEM	N	Mean± SEM	
RA Factor	40	3.11↓±24.011	40	9.89↓±13.39	0.806#
CRP	35	0.329↑±1.095	27	3.641↓±2.396	0.109#
ESR	40	2.357↑±3.674	40	4.450↓±3.002	0.155#

Data: Mean ± SEM↑ increase, ↓Decrease, #insignificant

Maximum patients registered in the age group of 41- 50 years (61.62%) followed by age between 31-40 years (20.93%), which shows *Amavata* is predominant in middle age group. This data is in accordance to the findings of modern science that the disease starts commonly, during the 3rd and 4th decade of life.[6,7]

It is observed that most of the patients were females (79.07%), supporting the established data that women are prone three times more than men.[8] 56.97% patients were chronic (more than a year) and 43.03% of patients showed chronicity of less than a year.

All enrolled patients (100%) had joint pain, while oedema, morning stiffness and tenderness were observed in 87.21%, 93.02% and 81.40% patients respectively. *Amla rasa pradhana ahara*, cold wind, day sleep were found to be aggravating factors in 76.74%, 75.58% and 47.67% of patients respectively. These all causative factors might cause *Stabdhata* and *Amavruddhi* at affected joints (due to *Khavaigunya*).Hot water fomentation, rest, walking and calm state of mind were found to be relieving factors in 88.37%, 38.37%, 19.77% and 13.95% of patients respectively. Hot water fomentation relives pain, inflammation, rigidity by the virtue of its *Swedana* property. Rest might cause relief in the patients who have *Kaphaja* predominance. Daily walking leads to A*gni Deepana* and it relieves *Ama*. The observations made in order to assess the role of psychic factors in the etio-pathogenesis of the disease revealed that maximum 62.79% of patients were anxious followed by tension and depression in 51.16% and 24.42% respectively. *Chinta, Bhaya, Krodha* etc. *Manasika Bhavas* are causative factors of indigestion of food.[9] The data obtained, verifies the role of *Manasika Nidana* in production of the disease *Amavata*. *Acharyas* also emphasized on this point by stating that *Chinta* is also a cause of *Rasavaha Sroto Dushti*.[10] The *Mala* of *Rasa* is *Kapha*, which also undergoes *Dushti*, and this *Dushita Rasa* will give nourishment to the subsequent *Dhatu* thus vitiating the other *Dhatus*., thus decreasing*Vyadhikshamatva*(immunity) of the person and thus making him more susceptible to diseases. After going through the etiological factors of *Amavata*, it is found that above factors individually or together lead to the *Kapha*or *Vata Prakopa* or both, that are responsible in manifestation of *Amavata*.

Both the trial drugs showed highly significant relief in cardinal symptoms. Significant relief in *Sandhishula* may be due to the *Vatahara* and *Vedanahara* properties of *Amavatari Rasa*. *Sandhishula* is the result of *Vata* vitiation. By virtue of *Snigdha* and *Vata Shamaka* nature, *Erandataila* might have played a role in pacifying *Vata*.[11]

Significant relief in *Sandhishotha* may be due to *Shothaghna* (anti-inflammatory) property of *Guggulu*[12]. *Dipana Pachana* property of *Amavatari Rasa* may be due to *Triphala*,[13] *Chitraka*,[14] *Guggulu*,[15] and *Eranda Taila*.[16] Thus the combination might be useful in removing *Ama,* which was accumulated in *Sandhi* causing reduction in *Shotha*. Significant relief in *Sandhigraha* may be due to the resolution of *Ama* in affected parts by the *Amahara* property of *Chitraka.* Tenderness is mainly due to swelling in joints, so

whenever swelling reduces it also decreases tenderness. *Kajjali* has *Sukshma* and *Srotoshodhaka* properties, which elevates *Agni* and inhibit formation of *Ama* along with *Dipana, Pachana, Amahara* and *Kaphavatahara* properties of *Amavatari Rasa* ingredients. *Amavata* is considered as *Amashayotha RasajaVikara Vyadhi*. *Dipana Pachana*is the choice of treatment in such condition. The pathology originates in the *Amashaya* due to poor digestion in presence of *Mandagni* ultimately resulting in formation of *Ama*. So, *Dipaniya* drugs will help in increasing *Agni* and further *Pachaniya* drugs facilitate digestion of *Ama*.

It is observed that except pain, stiffness, *Aruchi* and *Shoonangata;* all other symptoms showed better relief with ARM indicating providing symptomatic relief. Possibly, *Eranda, Chitraka, Triphala, Guggulu* might be responsible for such action.

Rheumatoid factor (RA) is defined as an antibody against the Fc portion of IgG. RA is done to measure the amount of the RF antibody in the blood. Data indicate that both groups have statistically insignificant improvement in countering this biological marker, but still more percentage of relief was observed with ARC in comparison to ARM. This further shows that classical preparation acts on root pathology and improves the condition by reversing the inflammatory pathology. No significant changes were observed in biochemical parameters indicating safety of the trial drugs.

CONCLUSION

On the basis of the study, it can be concluded that mercury has a definite role in providing benefit in chronic debilitating diseases as that of *Amavata*. Though there is no significant difference between the results of both groups, ARC appears to be influencing the cellular level of pathology, while ARM is helpful in providing mere symptomatic relief. This can be inferred that, presence of mercury is essential that helps in taking the drug to the cellular levels and breaking the pathology successfully. No untoward effects were noticed in any patients during the study period revealing safety of the drug. How mere presence of mercury influencing other components to reach the cellular level and reducing CRP and RA need to be evaluated through well designed experiments.

CONFLICTS OF INTEREST

Nil

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ABOUT AUTHORS

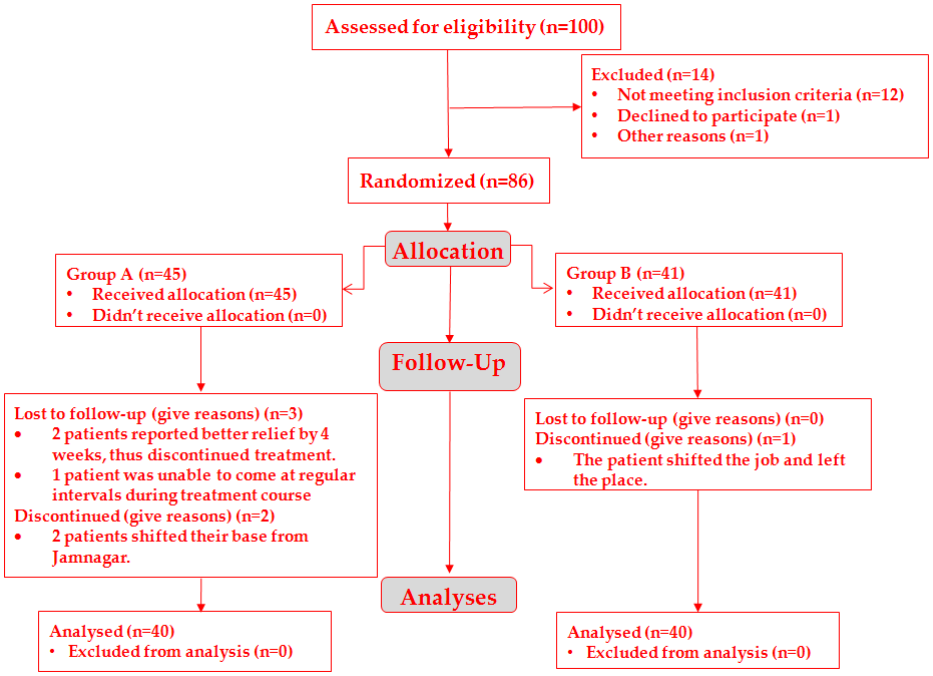
Dr. Sonam Bhinde MD (Ayu) is currently working as Lecturer, Manjushri Research Institute of Ayurvedic Sciences, Gandhi Nagar, Gujarat.

Dr. Galib R, MD (Ayu) PhD is currently serving as Associate Professor in department of Rasashastra and Bhaishajya Kalpana at All India Institute of Ayurveda, New Delhi. Previously, he served at IPGT & RA, Gujarat Ayurved University, Jamnagar till October 2016. He has more than 10 Years PG Teaching in concerned subject. Guided more than 20 theses, contributed around 10 chapters and investigated 3 projects as PI / Co-PI.

Dr. Prajapati PK, MD (Ayu) PhD is working as Dean, Prof and Head, Department of Rasashastra and Bhaishajya Kalpana, All India Institute of Ayurveda, New Delhi, India. He is a former Director of IPGT & RA, GAU Jamnagar and In - Charge Director of Pharmacy Gujarat Ayurved University Jamnagar, Head, Dept of RS & BK, IPGT& RA, Jamnagar. He obtained Teachers excellence award by CEE, Rasacharya Award for

contributions to Rasashastra, Nagarajuna Silver Medal for MD dissertation, Best Research article Award. He has authored 264 research articles and 3 monographs.

GRAPHICAL ABSTRACT



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