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PROTOCOL STUDY

Efficacy of *"Shunthi- Gokshur Kwath with Shunthi lepa and Shunthi-Guduchi Kwath with Shunthi lepa"* in Management of Rheumatoid Arthritis *(Amavata)* - Protocol for a Comparative Clinical Study

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ABSTRACT

Rheumatoid arthritis (RA) is an autoimmune inflammatory disease with a chronic nature and is associated with significant morbidity in today's era. The clinical features of RA are analogous to those of the *Ayurvedic* disease known as *Amavata*. This is an open-label, randomized clinical study that aims to compare the efficacy of *Shunthi-Gokshur Kwatha* with *Shunthi Lepa* and *Shunthi-Guduchi Kwatha* with *Shunthi Lepa* in reducing the disease activity score (DAS) in patients diagnosed with *Amavata*. A total of 72 participants aged 21–60 years, fulfilling ACR 2010 criteria and exhibiting classical *Amavata* symptoms, will be randomized into two groups. Group I will receive *Shunthi- Gokshur Kwatha* with *Shunthi Lepa*, and Group II will receive *Shunthi- Guduchi Kwatha* with *Shunthi Lepa* for a time period of 4 weeks. The primary outcome measure is the DAS-28 score, and the secondary outcome measures are RA factor, C-reactive protein, erythrocyte sedimentation rate, and symptoms of *amavata*. The assessment of primary and secondary outcome measures will be done at baseline, day 30, and day 60. The study protocol includes randomization, allocation concealment, and proper monitoring to ensure data reliability. The study results will contribute to the integration of *Ayurvedic* formulation in RA management.

1. INTRODUCTION

Rheumatoid arthritis (RA) is the most prevalent inflammatory arthritis and the second most common arthritis after osteoarthritis. It is an autoimmune illness marked by persistent inflammation and joint destruction.[1] Compared to men, women are impacted twice as frequently. The prevalence of RA is 460/100000 (0.46%) globally.[2] The frequency of RA peaks between the ages of 65 and 80, and the risk rises with age.[3] Ayurvedic physicians find a similarity between the presentation of RA and a clinical entity described as *Amavata* in classical Ayurveda texts. The primary pathogenic components of *Amavata* are *Ama and Vata*, the *ama*, which is resultant of derangement of *Agni,* particularly *Jatharagni*, while circulating through *dhamnies* find refuge in the *sleshma sthana* (*Amashya* and *Sandhi*), resulting in stiffness, body ache, anorexia, polydipsia, lassitude, heaviness of body, fever, indigestion of food, and swelling. Ayurvedic physicians refer to the condition as a *Chirkari* (chronic) sickness of *Madhyama Rogamarga* since it mostly affects joints. According to Ayurvedic classical texts, *Amavata* can be effectively treated with *Langhana* (fasting or light diet), *Deepana* (interventions that increase appetite), *Ama-pachana* (interventions that digest biotoxins), *Snehapana* (internal oleation), *Swedana* (fomentation), *Virechana* (therapeutic purgation), and *Basti* (medicated enema).[4] Shunthi (*Zingiber officinale*) is known for its anti-inflammatory and digestive properties,[5] while *Gokshur* (*Tribulus terrestris*) and *Guduchi* (*Tinospora cordifolia*) are used to enhance immunity and reduce inflammation.[6] The combination of *Ushna* Virya Shunthi[7] and *Sheeta* Virya Gokshura[8] thus creates a balanced formulation that simultaneously achieves *Amapachana*, *Vatahara*, *Shothahara*, and *Malavisarjana* — making Shunthi-Gokshura Kwatha a rational and classically validated intervention in *Amavata.* *Guduchi* (*Tinospora cordifolia*), possessing *Tikta Rasa*, *Ushna Virya*, and *Rasayana* property,[9] complements *Shunthi* through its potent *Amapachana*, *Tridoshahara*, and *Deepana* actions. The *Ushna* and

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Tikshna Guna[10] of the *Shunthi Lepa* enhance local microcirculation at the site of application, while facilitating penetration of the active phytoconstituents through the skin into the underlying inflamed tissue.

1.1. Objective

To compare the efficacy of *Shunthi-Gokshur Kwath with Shunthi lepa* and *Shunthi-Guduchi Kwath with Shunthi lepa* in the reduction of disease activity score (DAS)-28 Score in the management of *Amavata.*

2. MATERIALS AND METHODS

2.1. Study Design

Open-label, randomized, comparative clinical trial.

2.2. Study Site

Chaudhary Brahm Prakash Ayurved Charak Sansthan, New Delhi.

2.3. Sample Size

Sample size has been calculated by using the online sample calculator Openepi.[11]

This results in a Sample size of a total of 72 cases, including 10% of dropout rate, that is, (36 cases in each group) (table 1).

2.4. ACR/EULAR 2010 Classification Criteria for RA

Patients fulfilling ACR/EULAR 2010 criteria with a score of ≥6/10 will be included in the study. The scoring system is as follows:

2.5. Inclusion Criteria

1. Patients of either sex aged 21–60 years.
2. Patients fulfilling ACR 2010 criteria of RA (having a score ≥6/10).
3. Patients having the general clinical features of *amavata* as described in *Madhav Nidan (Ma. Ni. 25/6–10), namely, Sandhi- Saruja - Shoth (pain in joints),* along with one or more than one of the following clinical features -
   a. *Agnimandya* (~poor digestion)
   b. *Aruchi* (~anorexia)
   c. *Gaurava* (~heaviness of body)
   d. *Utsaha hani* (~lack of vigor)
   e. *Mukha vairasya* (~perverted taste).
4. Patients having blood pressure <150/90 mmHg.
5. Patients are willing to provide written informed consent for participation in the study.
6. Patients who have not taken any DMARD or Glucocorticoid for more than 15 days or are not taking any allopathic treatment at all.
7. Subjects who are not registered in any other research project.
8. Patients with a firm home address and contact no, which is readily accessible during the course of the trial.

2.6. Exclusion Criteria

1. Patients with crippling bone deformities
2. Seriously ill and moribund patients
3. Abnormal renal or hepatic functions, malignancy, cardiovascular disorder, HIV-acquired immunodeficiency syndrome, etc.
4. Patients planning to conceive in the near future (during the course of the trial)
5. Pregnant and lactating mothers
6. Any major psychiatric illness
7. Any other pre-existing illness that will require surgery during the course of the trial
8. Patients with any other concomitant arthropathy, such as Ankylosing Spondylosis, Osteomyelitis, Gouty Arthritis, Neoplasm of the spine, fractures, etc.

2.7. Withdrawal Criteria

The patient will be withdrawn from the trial if-

1. Individual's no compliance to treatment regimen.
2. Individuals who develop any other co-morbidity during the trial period that requires immediate pharmacological intervention.
3. Participants unwilling to continue the study for any reason will also be withdrawn. The reason for withdrawal will be recorded appropriately in the case record form (CRF).

2.8. Study Intervention

Shunthi-Gokshur Kwath will be given in a dose of 40 mL in Group I, and *Shunthi-Guduchi Kwath* in a dose of 40 mL in Group II. Both the study drugs will be administered twice a day orally before food for 4 weeks. *Shunthi* Lepa will be applied locally twice daily in both Group I and Group II on inflamed distal, proximal, and interphalangeal joints for 2 h. Details of the ingredients of both study interventions are given in [Tables 3 and 4], respectively. *Pathyapathya* (appropriate diet and lifestyle) will be advised to the participants of both groups.

2.8.1. Shunthi lepa

Shunthi Lepa is prepared by mixing hot water with *Shunthi Churna*. The thickness of *lepa* should be *Ardramahishcharmotsedha* (approx- 4–5 mm). The *lepa* was applied gently and evenly over the affected area, only like Distal phalangeal joints, Proximal phalangeal joints, Inter-phalangeal joints, etc. It is then freely allowed to dry, neither in sunlight nor in air from a fan. After getting dried and becoming stiff, the *lepa* applied was allowed to wash with lukewarm water. The same procedure was adopted for both groups (I and II).

2.8.2. Drug source

Quality-assured trial interventions will be procured from a GMP-certified Ayurveda Pharmaceutical Company. Voucher sample of the raw drug will be labeled and retained in the department of Kayachikitsa, Ch. Brahm Prakash Ayurved Charak Sansthan, New Delhi, for future references.

2.8.3. Randomization, design, and Allocation concealment

Done using the sequentially numbered, opaque, sealed envelopes method to ensure allocation concealment.

1. A sequence list of A and B assignments will be generated using the software.
2. The list will be kept confidential.
3. The assigned group (A or B) will be written on a small card for each position (1,2,3…) in the list.
4. The card will be folded and put into an opaque envelope
5. On the outside, only the sequential number will be written
6. The envelope will be stored in a locked cabinet.

2.8.4. Outcome measures

The primary outcome of this study is to change the DAS-28 score from Baseline. The outcome measures will be assessed at baseline, day 30, and day 60. Laboratory investigations, such as RA factor (Quantitative), erythrocyte sedimentation rate (ESR), and C-reactive protein (CRP) (quantitative), will be performed at baseline and on the 30th and 60th day. Blood Pressure will be measured at screening only to exclude poorly controlled hypertension. The schedule for enrolment,

study intervention administration, assessments, and follow-up visits is shown in Table 5 and Figure 1.

2.9. Drug Compliance

The compliance will be assessed at each scheduled follow-up visit by the MORISKY MEDICATION ADHERENCE SCALE.

2.10. Rescue Medicine

Participants enrolling in the experiment will be instructed to avoid using any other drugs on their own for any ailment and to consult with their treating physician for any symptoms or complaints. Any rescue medication administered will be reported in the corresponding column of the CRF.

2.11. Data Collection Methods

The necessary data, that is, demographics, medical history, clinical assessment, physical assessment, laboratory results, and assessment of outcome measures of the recruited participants, will be documented in a specially designed CRF at baseline and follow-up visits.

2.12. Data Management

At the study site, all study records will be safely stored. After collecting the data from the CRF, it will be entered into pre-specified Excel sheets. Proper data documentation will be ensured for appropriate interpretation, analysis, and verification. After the study is completed, the results will be analyzed and published without revealing the participants' personal identities. All participant data will be stored securely, in accordance with ethical requirements for data protection.

2.13. Statistical Analysis

All data collected during the trial will be entered into a pre-specified Microsoft Excel database. Statistical analysis will be performed by an independent biostatistician who will remain blinded to group allocation throughout the analysis phase. A two-tailed $P < 0.05$ will be considered statistically significant for all tests.

Baseline demographic and clinical characteristics of both groups will be summarized using descriptive statistics. Continuous variables (age, DAS-28, ESR, CRP, RA Factor, and SDAI) will be expressed as Mean ± Standard Deviation if normally distributed, or as Median with Interquartile Range if non-normally distributed. Categorical variables (symptom grading, Ayurvedic symptom categories) will be expressed as frequencies and percentages.

The normality of continuous outcome variables will be assessed using the Shapiro–Wilk test. Variables satisfying normality assumptions will be analyzed using parametric tests; those violating normality will be analyzed using their non-parametric equivalents.

Baseline comparability between Group I (Shunthi-Gokshur Kwatha) and Group II (Shunthi-Guduchi Kwatha) will be assessed using the Independent Samples *t*-test or Mann–Whitney U test for continuous variables, and the Chi-square test or Fisher's exact test for categorical variables.

2.13.1. Primary outcome

The primary outcome is the change in DAS-28 score from baseline. Intra-group comparison (pre- and post-treatment at Day 30 and Day 60) will be performed using the Paired *t*-test for normally distributed data, or the Wilcoxon Signed-Rank test for non-normally distributed data. Inter-group comparison of mean change in DAS-28 score between Group I and Group II at Day 30 and Day 60 will be conducted using the Independent Samples *t*-test or Mann–Whitney U test, as appropriate. For repeated-measures outcome data collected at 3 time points (Baseline, Day 30, Day 60), a repeated-measures analysis of variance will be applied if normality and sphericity assumptions are met.

2.13.2. Secondary outcomes

Including SDAI score, RA Factor (Quantitative), CRP (Quantitative), and ESR – will be analyzed using the same parametric or non-parametric framework described for the primary outcome. Intra-group changes will be assessed using the Paired *t*-test or Wilcoxon Signed-Rank test, and inter-group differences will be evaluated using the Independent Samples t-test or Mann–Whitney U test. Subjective Ayurvedic symptoms (Sandhi-Saruja-Shotha, Agnimandya, Aruchi, Gaurava, Utsaha Hani, and Mukha Vairasya) will be graded on a four-point ordinal scale and analyzed using the Wilcoxon Signed-Rank test for intra-group comparison and the Mann–Whitney U test for inter-group comparison. Frequency data for categorical outcomes will be compared using the Chi-square test or Fisher's Exact test, as appropriate.

2.14. Data Monitoring

Data monitoring will fall under the purview of the principal investigator.

2.15. Management of Adverse Events (AEs)

Any AEs, adverse drug reactions, or AEs (SAEs) that the participant reports or that the physician observes during the trial period will be recorded and appropriately and promptly managed. The Ethics Committee will be informed of this within a day.

2.16. Ethics and Dissemination

The study protocol has been approved by the Institutional Ethics Committee (F2(1047)/25-26CBPACSPrinc./IEC/Proceedings/25-26/6342-44, dated December 11, 2025. The study is registered prospectively at the Clinical Trial Registry of India (CTRI/2026/01/101038). The investigators will obtain informed consent from the eligible subjects before enrolment. The research study outcomes will be published in a reputable indexed journal.

2.17. Protocol Amendments

Any substantial amendment to this protocol that may affect the safety of participants, the scientific value of the study, the conduct of the study, or the rights and welfare of the participants will be submitted to the Institutional Ethics Committee (IEC) for review and written approval before implementation.

2.18. Confidentiality

Participants' personal information will be kept private. Members of the Institutional Ethics Committee may review the medical records to determine whether the study was conducted properly.

2.19. Access to Data

The gathered data will only be evaluated by the study's investigators. Data about statistical analysis will be evaluated by a separate biostatistician.

2.20. Ancillary and Post-Trial Care

No ancillary and post-trial care is planned in the study for the participants.

3. DISCUSSION

This study is designed to evaluate the comparative efficacy of two traditional *Ayurvedic* formulations combined with topical therapy in managing *Amavata*, a condition analogous to RA. The therapeutic rationale is grounded in the anti-inflammatory, immunomodulatory, and digestive properties of the herbal ingredients – *Shunthi, Gokshur*, and *Guduchi* – which have been traditionally used to address the pathophysiology of *Amavata* in *Ayurveda.*

By incorporating both systemic oral *Kwatha* and localized *Shunthi Lepa* application, the intervention aims to target both systemic and joint-specific inflammation and symptoms. The use of validated clinical and laboratory parameters, such as DAS-28, RA factor levels, CRP, and ESR, will enable objective assessment of treatment efficacy.

3.1. Probable Mode of Action: *Shunthi - Gokshur Kwatha* – Group I

Gokshur (*Tribulus terrestris*), possessing *Madhura Rasa*, *Guru* and *Snigdha Guna*, *Sheeta Virya*, and *Madhura Vipaka*,[38] occupies a position that is complementary and balancing to *Shunthi* in the *Shunthi-Gokshur Kwatha* formulation. While *Shunthi* provides *Ushna Virya*-mediated *Amapachana* and *Vatahara* action,[39] *Gokshur's Sheeta Virya* simultaneously mitigates the potential *Pitta*-aggravating effects of *Shunthi*, making this combination a balanced and well-tolerated formulation as per *Ayurvedic* drug synergy. Its *Shothhara, Vatahara*, and *Deepana* properties,[19] combined with its *Mutravirajaniya* action, facilitate the elimination of metabolic waste products (*Mala Visarjana*) through the urinary route, thereby reducing the *Ama* load in the body.

Pharmacologically, the steroidal saponins (protodioscin, dioscin), flavonoids, and alkaloids in *Tribulus terrestris* demonstrate significant anti-inflammatory activity by inhibiting COX-2 expression and reducing PGE2 synthesis.[20] Its immunomodulatory activity modulates abnormal immune responses central to RA pathogenesis. Diuretic properties of *Gokshur* enhance renal clearance of inflammatory mediators and uric acid, providing additional benefit, particularly in patients with concomitant metabolic disturbances. Cardiotonic and hypotensive properties serve as ancillary benefits in RA patients who are at higher cardiovascular risk. The anti-arthritic and chondroprotective effects noted in experimental models suggest a potential role in retarding joint destruction at the cartilage level.

3.2. Probable Mode of Action: *Shunthi - Guduchi Kwatha* – Group II

Guduchi (Tinospora cordifolia), classified among the *Rasayana* and *Tridoshaghna* drugs of *Ayurveda*, possesses *Tikta* and *Katu Rasa, Guru* and *Snigdha Guna*, *Ushna Virya*, and *Madhura Vipaka*. Its well-established *Amapachana*, *Vatashamaka*, *Balya*, *Vedanasthapana*, and *Deepana* properties make it an ideal complementary drug to *Shunthi* in the *Shunthi-Guduchi Kwatha*. Unlike *Gokshur*, which is *Sheeta Virya*, *Guduchi* shares *Ushna Virya* with *Shunthi*, creating a more potent *Amapachana* and *Agnideepana* combination – potentially offering superior efficacy in patients with predominant *Ama* and *Mandagni*.

Tinospora cordifolia is rich in alkaloids (berberine, palmatine, tinosporin), glycosides (tinosporaside, cordifolioside), diterpenoid lactones (columbin, tinosporon), and polysaccharides.[6] These constituents collectively produce broad-spectrum pharmacological actions relevant to RA management. Its immunomodulatory action occurs through stimulation of macrophage activation, enhancement of phagocytic activity, and modulation of T-lymphocyte responses – effectively correcting the dysregulated immune milieu of RA.[30] Anti-inflammatory effects are mediated through inhibition of COX-2, NF-κB, and pro-inflammatory cytokines (tumor necrosis factor alpha, interleukin (IL)-1β, IL-6). Anti-arthritic effects observed in adjuvant-induced arthritis models suggest a capacity to reduce synovial inflammation and joint erosion.[27]

3.3. Probable Mode of Action: Shunthi Lepa (Topical Application) – Both Groups

Shunthi Lepa is applied locally to the inflamed distal, proximal, and interphalangeal joints at a thickness of *Ardramahishcharmotsedha* (approximately 4–5 mm). It functions as a targeted local intervention operating through the principle of *Bahya Chikitsa*. In Ayurvedic pharmacology, *Lepa* produces its therapeutic effects through the *Twak* and the underlying *Sira,* which facilitates transdermal absorption of bioactive phytoconstituents into inflamed subdermal and synovial tissues.

The *Ushna* and *Tikshna Guna* of *Shunthi Lepa* enhance the microcirculation at the application site through vasodilation, thereby increasing the delivery of immune-regulatory cells and facilitating the clearance of accumulated Ama and inflammatory exudates from the joint space. This *Shothahara* and *Vedanasthapana* effect is analogous to the counter-irritant mechanism of topical preparations in modern pharmacology, wherein local hyperemia reduces the perception of deep pain. The drying action of the *Lepa* as it sets on the skin also produces a mild pressure effect akin to compression, reducing edema and *Shotha*.

Transdermally absorbed gingerols and shogaols from *Shunthi Lepa* inhibit local COX-2 activity and PGE2 synthesis in synovial tissues, reducing local inflammatory mediator concentration.[10]

4. CONCLUSION

This study is a contribution to the growing body of evidence supporting the integration of validated Ayurvedic formulations into contemporary practice. Both *Shunthi-Gokshur Kwatha* and *Shunthi-Guduchi Kwatha*, each combined with *Shunthi Lepa*, present pharmacologically well-reasoned interventions for *Amavata*. The probable modes of action address both the *Ayurvedic* pathogenesis and the modern immunopathological mechanisms of RA. The randomized trial design, with standardized outcome measures and allocation concealment, will generate reliable evidence to guide Ayurvedic clinical practice.

5. ACKNOWLEDGMENTS

Nil.

6. AUTHORS' CONTRIBUTIONS

All authors give equal contribution in making of this manuscript.

7. FUNDING

Nil.

8. ETHICAL STATEMENT

Institutional Ethical Committee approval is taken for this study with Trial Registration Number, CTRI/2026/01/101038.

9. CONFLICT OF INTERESTS

The authors declare no conflicts of interest regarding the publication of this paper.

10. DATA AVAILABILITY STATEMENT

The data analyzed in this review were obtained from publicly available sources, including peer-reviewed articles, observational studies, and surveys accessible through databases.

11. DISCLAIMER/VIEW AND OPINIONS

The opinions expressed in this article are solely those of the authors and do not reflect the views of the International Research Journal of Ayurveda and Yoga or its editorial board.

12. AI-USE DECLARATION

The authors declare that no generative AI tools were used to create scientific content, interpret data, or draft any sections of this manuscript. AI-based tools were used solely for minor language and grammar refinements to improve clarity and readability. All scientific content, analysis, and conclusions remain the sole responsibility of the author.

13. PUBLISHERS NOTE

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Table 1: Sample Size

Type of outcome variable	Continuous DAS-28 score value
Mean for group A	3.500
Mean for group B	2.829
Standard deviation(σ2) for group A	0.780
Standard deviation(σ2) for group B	0.880
Power	90%
Confidence interval	95%
Dropout %	10%

DAS: Disease activity score

Table 2: ACR/EULAR 2010 Classification Criteria for Rheumatoid Arthritis

Domain/criterion	Score
A. Joint involvement	
1 large joint	0
2–10 large joints	1
1–3 small joints (with or without large joint involvement)	2
4–10 small joints (with or without large joint involvement)	3
>10 joints (at least 1 small joint)	5
B. Serology (at least 1 test required)	
Negative RF and negative Anti-CCP	0
Low positive RF or low positive Anti-CCP	2
High positive RF or high positive Anti-CCP	3
C. Acute-phase reactants (at least 1 test required)	
Normal CRP and normal ESR	0
Abnormal CRP or abnormal ESR	1
D. Duration of symptoms	
<6 weeks	0
≥6 weeks	1
Total score (0–10): Score≥6/10=Definite RA	Max=10

RF: Rheumatoid factor, Anti-CCP: Anti-cyclic citrullinated peptide antibody, CRP: C-reactive protein, ESR: Erythrocyte sedimentation rate

Table 3: Ingredients of *Shunthi-Gokshur Kwatha*

Drug name	Botanical name and family	Karmas beneficial in amavata	*Rasa panchak*	Activities of drug
Shunthi	*Zingiber officinale* Roxb Family- Zingiberaceae	*Dipaniya, shothgana, shleshmahara vedanasthapan*	*Rasa: Katu* *Guna: Laghu, Snigdha* *Virya: Ushana* *Vipaka: Madhura* Prabhav: Vedanasthapana	Anti- inflammatory[5] Anti- oxidant,[12] Anti- bacterialactivity,[13] Hypolipidemic,[14] Anti- atherosclerotic,[15] Anti- diabetic activity,[16] Hepatoprotective,[17] Hypoglycemic[18]
Gokshur	*Tribulus terristris* (Linn.) Family- Zygophyllaceae	*Shothhara, Vatahara, Dipana*	*Rasa: Madhura* *Guna: Guru, Snigdha* *Virya: Sheet* *Vipaka: Madhura* Prabhav: Mutravirajaniya	Antibacterial activity,[19] Anti- fungal activity,[20] Anti- inflammatory,[21] Cardiotonic activity,[22] Hypotensive Activity,[23] Diuretic activity,[24] Antidiabetic activity[25] Immunomodulatory.[26]

Table 4: Ingredients of *Shunthi-Guduchi Kwatha*

Drug name	Botanical name and family	karmas beneficial in Amavata	Ras panchak	Activities of drug
Shunthi	*Zingiber officinale* Roxb Family- Zingiberaceae	*Dipaniya* *shothgana* *shleshmahara* *vedanasthapan*	*Rasa: Katu* *Guna: Laghu, Snigdha* *Virya: Ushana* *Vipaka: Madhura* *Prabhav: Vedanasthapana*	Anti- inflammatory, Anti- oxidant, Antibacterial activity, Hypolipidemic, Anti- atherosclerotic, Anti- diabetic activity, Hepatoprotective, Hypoglycemic
Guduchi	*Tinospora cordyfolia* (Willd.) Miers Family-Menispermaceae	*Vatashamak* *Balya* *Vedanasthapan* *Ama pachana*	*Rasa: Katu, Tikta* *Guna: Guru, Snigdh* *Virya: Ushna* *Vipaka: Madhur* *Prabhav: Tridoshaghna, Rasayana*	Anti-inflammmatory[27] Anti-Arthritic[28] Anti-Osteoporic[29] Immunomodulator[30] Anti- oxidant[31] Anti- Neoplatic[32] Anti-Allergic[33] Anti-pyretic[34] Anti- Infective[35] Hepato- protective[36] Anti-Hyperglycemic[37]

Table 5: Study schedule

Steps	Screening	Day 1	Day 9	Day 16	Day 23	Day 30	Day 45	Day 60
	☑							
History	☑							
Patient Enrolment Sign consent		☑						
Drug intervention			**2nd to 30th day**					
Assessment of symptoms	☑		☑	☑	☑	☑	☑	☑
DAS-28 score	☑	☑				☑		☑
RA factor (quantitative)	☑	☑						☑
CRP (quantitative)	☑	☑				☑		☑
ESR	☑	☑				☑		☑
Follow-up			☑	☑	☑	☑	☑	☑

RA: Rheumatoid arthritis, CRP: C-reactive protein, ESR: Erythrocyte sedimentation rate, DAS: Disease activity score, ☑: recorded

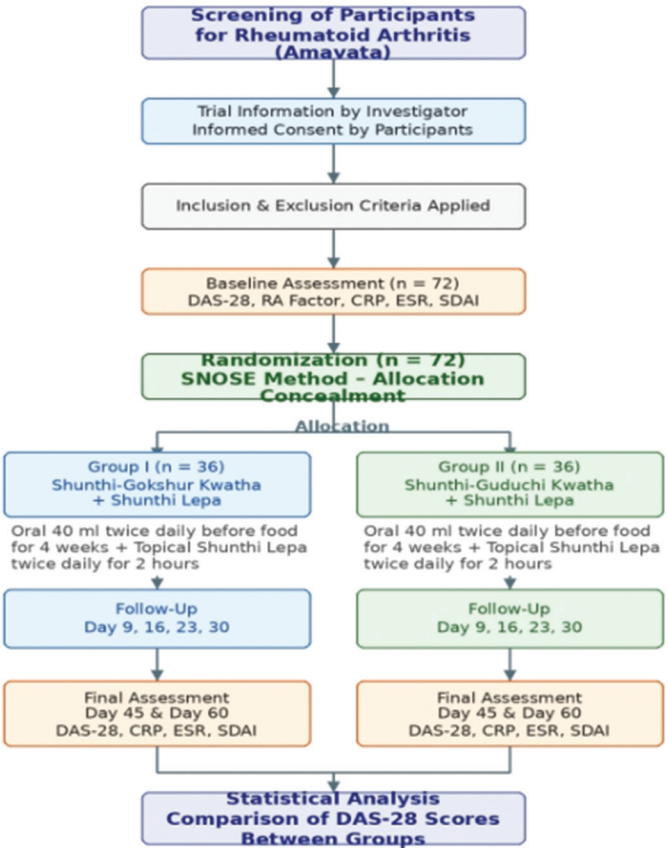

Figure 1: CONSORT flow diagram – Amavata (Rheumatoid arthritis) clinical trial