Clinical Evaluation of Classical Ayurvedic Formulations

Simhanada Guggulu and Brihat Saindhavadi Taila in the Management of Rheumatoid Arthritis (Amavata): A Multicentric Open Label Prospective Study

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ABSTRACT

Introduction: Rheumatoid arthritis (RA) is a chronic, progressive, inflammatory autoimmune disease associated with articular, extra-articular, and systemic effects. Similar symptoms are found in Amavata described in Ayurveda. Simhanada Guggulu and Brihat Saindhavadi Taila are classical formulations that are used commonly in the management of Amavata.

Aims and objectives: To assess the clinical efficacy and safety of the classical Ayurvedic formulations Simhanada Guggulu and Brihat Saindhavadi Taila in patients with RA.

Materials and methods: A prospective, open label, multicenter study was carried out at two peripheral centers of the Central Council for Research in Ayurvedic Sciences (CCRAS). A total of 111 patients were administered Simhanada Guggulu and Brihat Saindhavadi Taila in the dose of 1.5 gm (3 tablets of 500 mg each) twice daily after food with lukewarm water and local application twice a day respectively, for a period of 12 weeks. Clinical assessment of symptoms, disease activity score-28 (DAS-28), short form 36 (SF-36), and disability index scoring were done at the baseline and at every subsequent visit at an interval of 14 days up to the 12th week and also in the follow-up without medication at the end of the 14th week. Paired sample t-test was used to compare mean change from baseline to 12th and 14th week respectively.

Results: At the end of 12 weeks, statistically significant changes in symptoms, DAS 28, SF-36, and disability index score with p-value <0.001 were observed, compared with baseline. No adverse drug reaction (ADR)/adverse events (AEs) were reported during and after the trial.

Conclusion: Simhanada Guggulu and Brihat Saindhavadi Taila administered together in the above-mentioned dose were found effective, safe, and tolerable in patients with RA.

Keywords: Amavata, Brihat saindhavadi taila, Rheumatoid Arthritis, Simhanada Guggulu.


Source of support: Nil

Conflict of interest: None

INTRODUCTION

Rheumatoid arthritis is a chronic, progressive, inflammatory autoimmune disease associated with articular, extra-articular, and systemic effects. Rheumatoid arthritis has a worldwide prevalence of approximately 0.5 to 1% among adults. Symptoms may vary from person to person; some patients have mild self-limited disease, while many experience joint destruction, severe physical disability, and multiple comorbidities. The pathobiology of RA is multifaceted and involves T-cells, B-cells, and the complex interaction of many pro-inflammatory cytokines, including tumor necrosis factor-α and interleukin (IL)-6. These cytokines are messengers that activate and differentiate effector cells that cause local and systemic symptoms associated with this disease. The RA is associated with a heavy burden on society in terms of disability and health and economic costs as RA tends to be progressive in nature, involving a worsening of symptoms over time, and often begins for many people during the early or middle years of life. The disease often has a long-term impact on functioning, which translates to a considerable social and economic cost.
Major clinical features of RA include joint pain associated with redness, swelling, and stiffness, symmetric polyarthritis, joint deformity, fatigue, and fever, which are symptomatically similar to the disease Amavata. When Koshtigata Ama is propelled by the Vata to Sthika through circulatory channels, Ama gets lodged in Shleshasthata like Sandhi and Uras producing symptoms, such as Angnarda (generalized body ache), Gaurava (heaviness in body), Jwara (fever), Angasunata (swelling), and Sanditishwola (joint pain), etc.5 Current treatment protocol in modern medicine involves use of disease-modifying anti-rheumatic drugs, which suppress the immune system and, while effective in this regard, leads to an increased risk of infections. These drugs are also associated with side effects including nausea, abdominal pain, and serious lung and liver toxicities, and, hence, other treatment modalities need to be explored.

This study was designed to assess the clinical efficacy and safety of the classical Ayurvedic formulations, Simhanaada Guggulu and Brihat Saindhavadi Taila, which are widely used in the management of RA.

OBJECTIVES

Primary Objective

To assess the clinical efficacy of Simhanaada Guggulu and Brihat Saindhavadi Taila in the management of RA (Amavata).

Secondary Objective

To assess the clinical safety of Simhanaada Guggulu and Brihat Saindhavadi Taila in patients with RA (Amavata).

MATERIALS AND METHODS

Study Design

The study was a prospective, open label, multicenter trial executed at two peripheral centers of the CCRAS, Ministry of AYUSH, namely, National Ayurveda Research Institute for Panchakarma (NARIP), Cheruthuruthy, and Research Ayurveda Regional Institute for Gastro-Intestinal Disorders, Guwahati (RARIGID), Guwahati, India, for a duration of 14 weeks (12 weeks intervention followed by 2-weeks follow-up period without intervention). The study was approved by the Institutional Ethics Committee of both the centers and was done in accordance with World Health Organization Good Clinical Practice Guidelines. The clinical trial has also been registered in the Clinical Trial Registry of India (CTRI/2012/03/002534).

Study Participants

A total of 114 participants were enrolled in the trial after obtaining the written informed consent and 111 completed the trial. Totally, 58 patients were from the NARIP, Cheruthuruthy, Kerala, India, and 53 from RARIGID, Guwahati, India. Patients were screened in accordance with the inclusion and exclusion criteria mentioned in the protocol.

Inclusion Criteria

Patients of either sex with age in the range of 20 to 60 years with presence of any four out of the following criteria (according to 1987, revised criteria of American College of Rheumatology): (a) Morning stiffness: stiffness in and around joints lasting one hour before maximal improvement (more than 6 weeks duration), (b) arthritis of three or more joints, at least three joint areas, observed by physician, having pain with soft tissue swelling or joint effusion, not just bony overgrowth (more than 6 weeks duration), (c) arthritis of hand joints, at least one area in wrist and hand is swollen (more than 6 weeks duration), (d) symmetric arthritis (more than 6 weeks duration), (e) presence of rheumatoid nodules, (f) serum rheumatoid factor-positive, and (g) typical radiographic changes of arthritis on posteroanterior view of hand and wrist radiograph that must include erosions or unequivocal bony decalcification, localized in or adjacent to involved joints.

Exclusion Criteria

Patients who have developed complications of RA or who are unable to walk without support and/or confined to the wheelchair, those with structural deformity as the complication of RA, and patients diagnosed with other arthritis like gouty arthritis, tuberculous arthritis, etc., were excluded. Moreover, patients with evidence of malignancy, those suffering from any other major systemic illness necessitating long-term therapy, or with past history of atrial fibrillation, coronary artery disease, acute coronary syndrome, myocardial infarction, stroke, or severe arrhythmia in the last 6 months were also excluded. Further, symptomatic patients with clinical evidence of heart failure, patients with poorly controlled hypertension defined as systolic blood pressure >160 mm Hg and diastolic blood pressure >100 mm Hg and patients with blood sugar fasting level >126 mg/dL or blood sugar postprandial >200 mg/dL were also excluded.

Patients on prolonged (≥6 weeks) medication with corticosteroids, antidepressants, or anticholinergics were excluded from the study to safeguard the outcomes of the study formulations. Patients with concurrent serious hepatic disorder defined as aspartate aminotransferase and/or alanine aminotransferase, total bilirubin, alkaline phosphatase >2 times upper normal limit, or renal disorders defined as serum creatinine >12 mg/dL, total serum cholesterol and/or serum triglycerides > 250 mg/dL.
severe pulmonary dysfunction (uncontrolled bronchial asthma and/or chronic obstructive pulmonary disease) were also excluded. Alcoholic or drug abusers, pregnant and lactating women, and patients who have the past record of hypersensitivity to any of the ingredients of the trial medications were also excluded. Patients who have participated in any other clinical trial during the past 6 months were also excluded from the study.

Study Interventions

The formulations fulfilling the physicochemical standards and quality parameters and prepared as per standard operating procedures were procured from Good Manufacturing Practices-certified companies. Simhanaada Guggulu in the dose of 1.5 gm (3 tablets of 500 mg each) was given twice a day after food with lukewarm water as anupana for a period of 12 weeks. Brihat Saindhavadi Taila was applied locally on the affected joint twice a day for a period of 12 weeks. Both these drugs are mentioned in Ayurveda classics and have been in practice since long. The drug compliance was assessed on each visit during the study.

Study Procedure

On the enrolment day at baseline (Visit 1), patient’s demographic profile, medical history, family history particularly related to RA, assessment of DAS-28, disability index (The Indian Health Assessment Questionnaire), SF-36 scoring, and assessment of Ayurvedic parameters were recorded in the prescribed format. Subsequent visits were planned at an interval of 2 weeks [14th day (Visit 2), 28th day (Visit 3), 42nd day (Visit 4), 56th day (Visit 5), 70th day (Visit 6), and 84th day (Visit 7)]. Patients were assessed and given study medications at each subsequent visit until the 84th day and follow-up without medication was done at 98th day (Visit 8).

Details of clinical assessment and study schedule are given in Flow Chart 1.

At the study site, data of all the patients were recorded in predesigned Case Report Forms (CRFs) and were also entered in electronic formats (e-formats) designed in MS-Excel with many data validation checks to ensure correct data entry. The e-formats and Xerox of the CRFs along with the scorings and laboratory investigations reports of the patients were sent by the participating centers to the Council's headquarters.

Flow Chart 2 shows the outflow of the patients in the study.

Outcome Measures

Primary Outcome Measure

Reduction in DAS-28 score.

Secondary Outcome Measures

- Change in disability index (The Indian Health Assessment Questionnaire),
• Change in acute phase reactants—erythrocyte sedimentation rate (ESR) and C-reactive protein,
• Change in Health Questionnaire SF-36.

Statistical Analysis

Primary outcome and secondary outcome measures, i.e., DAS-28 score and change in disability index, acute phase reactants, and change in Health Questionnaire, SF-36, were analyzed as mean change in the response from baseline to 84th day by using paired t-test and chi-squared test. A p-value of <0.05 was considered significant. Symptomatic relief was assessed as percentage change from the baseline and the 84th day in terms of symptoms. Statistical analysis was performed using Statistical Package for the Social Sciences version 15.0.

OBSERVATION AND RESULTS

Results

Data of a total of 111 patients (15 males and 96 females) were used for statistical analysis. Table 1 shows the demographic profile of the patients. Majority of the patients were observed to be belonging to Vata-Pittaaja Prakrti (43.2%) followed by Pitta-Kaphaja Prakrti (21.6%). About 80 (72.1%) patients were hailing from above-poverty line.

It was observed from the data that 99 (89.2%) patients were married. Totally, 83 (74.8%) patients were literate enough to read and write (Table 1). Maximum number of patients, 70 (63.1), were housewives, who indulged in domestic work, which included physical labor also. It was also noticed that 100 (90.1%) patients were nonvegetarians, addiction of any kind was not found in 90.1% of cases, while smoking and chewing tobacco were observed in 3.6 and 6.3% respectively (Table 2).

Simhanada Guggulu and Brihat Saindhavadi Taila were found to have a significant effect on the common complaints faced by patients suffering from RA. In musculoskeletal examination, symmetrical polyarthritis was observed in 100% of cases in the baseline and in 92.7% after 84 days. Swelling was present in 94.6% cases initially, which reduced to 68.5% by the end of the trial. Morning stiffness was observed in 96.4% at the baseline and 54.1% at the end. Joint tenderness was observed as the major symptom in all the patients, and it was observed in only 99 (89.2%) at the end of the trial period. Fever was a major constitutional symptom in 49 (44.1%) patients and was present only in 19 (17.1%) on the 84th day. The effect of trial medications is given in Table 3 and Graph 1.

Table 2: Personal habits

<table>
<thead>
<tr>
<th>Diet</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Vegetarian</td>
<td>11 (9.9%)</td>
</tr>
<tr>
<td>Nonvegetarian</td>
<td>100 (90.1%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sleep</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>76 (68.5%)</td>
</tr>
<tr>
<td>Disturbed</td>
<td>35 (31.5%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Addiction</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoking</td>
<td>4 (3.6%)</td>
</tr>
<tr>
<td>Tobacco</td>
<td>7 (6.3%)</td>
</tr>
<tr>
<td>None</td>
<td>100 (90.1%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Stress</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimal</td>
<td>42 (37.8%)</td>
</tr>
<tr>
<td>Moderate</td>
<td>68 (61.3%)</td>
</tr>
<tr>
<td>Too much</td>
<td>1 (0.9%)</td>
</tr>
</tbody>
</table>

Table 3: Musculoskeletal symptoms

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Baseline 14 weeks (follow-up without medication)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain in joints</td>
<td>111 (100.0%) 110 (99.1%) 109 (98.2%)</td>
</tr>
<tr>
<td>Swelling in joints</td>
<td>105 (94.6%)  105 (94.6%)  105 (94.6%)</td>
</tr>
<tr>
<td>Morning stiffness</td>
<td>107 (96.4%)  107 (96.4%)  107 (96.4%)</td>
</tr>
<tr>
<td>Tenderness</td>
<td>111 (100%)   111 (100%)   111 (100%)</td>
</tr>
<tr>
<td>Fever</td>
<td>49 (44.1%)   49 (44.1%)   49 (44.1%)</td>
</tr>
<tr>
<td>Malaise</td>
<td>104 (93.7%)  104 (93.7%)  104 (93.7%)</td>
</tr>
</tbody>
</table>

Values are expressed as n (%)
was found in 104 (93.7%) patients at the baseline, which got reduced to 99 (89.2%) after the trial.

Effect of Trial Medication on Outcomes

Effect of the study medications, Simhanada Guggulu and Brihat Saindhavadi Taila, on DAS-28, SF-36, and disability index was assessed by paired t-test from the data recorded at the baseline and on 84th day and is shown in Table 4 and Graph 2.

Simhanada Guggulu and Brihat Saindhavadi Taila provided significant change in DAS-28, SF-36, and disability scores at the end of trial period. Change in DAS-28 was considered as the primary outcome and mean was recorded as 6.81 (0.79) at baseline and 5.07 (1.12) at the end of 84th day. The secondary outcomes were improvement in disability index and SF-36 scores. The mean of disability index was observed as 1.32 (0.58) at baseline and 0.7485 (0.48) on the 84th day, which was significant with p-value <0.001. Trial medications produced significant improvement in all 8 parameters of the SF-36 questionnaire, viz., physical functioning (p-value <0.001), limitations due to physical health (p-value <0.001), limitations due to emotional problems (p-value <0.05), energy/fatigue (p-value <0.001), emotional wellbeing (p-value <0.001), social functioning (p-value <0.001), pain (p-value <0.001), and general health (p-value <0.001).

Safety Profile

The liver function tests (LFTs); serum glutamic oxaloacetic transaminase (SGOT), serum glutamic pyruvic transaminase (SGPT), total protein, serum albumin, serum globulin, conjugated bilirubin, unconjugated bilirubin, and serum alkaline phosphatase] and renal function tests (RFTs; blood urea, serum uric acid, serum

Table 4: Effect of trial medicine on outcome measures

<table>
<thead>
<tr>
<th>Score</th>
<th>Mean at baseline</th>
<th>Mean at 84th day</th>
<th>Mean at the end of 14 weeks (follow-up without medication)</th>
<th>t-value</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>DAS-28</td>
<td>6.81 (0.79)</td>
<td>5.07 (1.12)</td>
<td>4.90 (1.12)</td>
<td>19.171</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Disability index</td>
<td>1.32 (0.58)</td>
<td>0.7485 (0.48)</td>
<td>0.7252 (0.52)</td>
<td>12.117</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>SF-36 health survey questionnaire</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical functioning</td>
<td>30.23 (19.3)</td>
<td>66.75 (27.29)</td>
<td>68.15 (29.2)</td>
<td>15.305</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Limitations due to physical health</td>
<td>30.23 (19.358)</td>
<td>66.75 (27.296)</td>
<td>41.22 (42.859)</td>
<td>5.081</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Limitations due to emotional problems</td>
<td>20.72 (32.428)</td>
<td>33.78 (37.770)</td>
<td>36.04 (39.730)</td>
<td>3.499</td>
<td>0.001</td>
</tr>
<tr>
<td>Energy/fatigue</td>
<td>42.57 (14.092)</td>
<td>53.24 (12.278)</td>
<td>52.97 (13.624)</td>
<td>7.136</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Emotional well-being</td>
<td>52.22 (14.82)</td>
<td>57.59 (13.5)</td>
<td>59.42 (14.0)</td>
<td>3.816</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Social functioning</td>
<td>48.874 (22.0762)</td>
<td>63.288 (21.6033)</td>
<td>63.51 (19.881)</td>
<td>5.900</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Pain</td>
<td>44.57 (21.25)</td>
<td>64.55 (20.17)</td>
<td>64.5 (21.32)</td>
<td>11.359</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>General health</td>
<td>35.23 (16.5)</td>
<td>40.99 (16.5)</td>
<td>40.14 (16.4)</td>
<td>3.690</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Values are expressed as mean (standard deviation); *Compared using chi-square test at baseline and 84th day; **p-value <0.05 has been considered as significant.
creatinine) values were recorded before and after the trial, and the values were compared using paired t-test and p-value was observed to be >0.05, which proves that the trial medications do not have any adverse effect on the liver and kidney. No AE/ADR was observed in any patient during the study (Graphs 4, 5 and Table 5).

### DISCUSSION

The RA is one among the inflammatory diseases of the joints and may result in physical disability and impaired quality-of-life, thereby contributing indirectly to the economic burden of the disease. In India, the prevalence has
been estimated to be 0.7%. Current modern treatment principles for RA include use of disease-modifying anti-rheumatic drugs, nonsteroidal anti-inflammatory drugs, and glucocorticoids, as well as nonpharmacological measures, such as physical, occupational, and psychological therapeutic approaches.

Medicines mentioned in the context of Amavata can be seen to have specific action on amasaya (where the formation of ama occurs), rasadhatu, and in other kapha sthanas, where it acts by producing ama pachana and srotosodhana.

**Observed Effect of Trial Medications**

In this study, the majority of the patients were females (86.5%), and in the middle-aged group, which might be attributed to the hormonal influences that control all their functioning in that phase of life. About 90.1% of patients were nonvegetarians and this can be believed to be a cause and trigger for RA. Varying levels of stress were seen in the patients with 61.5% having moderate levels of stress and 37.8% having minimal stress. Stress can be directly related to flare-ups of disease activity due to the effect of stress hormones that disturb the immune system, causing it to release cytokines, which are chemicals that promote inflammation.

The symptoms seen in the patients of this trial were joint pain, swelling in the joints, morning stiffness, tenderness in joints, fever, and malaise. All these symptoms improved significantly after treatment for 84 days. In the disease Amavata, the symptoms are produced as a result of accumulation of Ama in Koshta primarily and secondarily in other kapha sthanas, such as rasadhatu and sandhi. Thus, the symptoms, such as jvara, alasya, sandhi sula, stabhidasandhi, and sandhi sopha are produced. Swelling in the joints, the predominant lakshana in 94.6% patients is a reflection of rasagata ama, which has undergone significant reduction to 68.5% after the trial. The intervention has provided statistically significant change in DAS-28 score, disability index, change in acute phase reactants like ESR and change in health questionnaire SF-36, which is a direct demonstration of its efficacy in rheumatic diseases (Graph 3).

The fact that trial medications provided significant relief in the clinical features indicate that Simhanada Guggulu has succeeded in producing deepana and amapachan to the same rasa in koshta and rasavaha srotas. Brihat Saindhavadi Taila has ingredients that are tikshna, ushna, and ruksha swabhava in nature, and therefore, has succeeded in reducing the swelling and pain in joints by producing srotosodhana and amapachana.

No AE/ADR was noticed in any patient during the study. The LFTs and RFTs values remained within limits during the entire trial period.

The ingredients of Simhanada Guggulu are Triphala, Eranda Taila, Sudha Guggulu, and Sudha Gandhaka. Triphala has laghu and ruksha rasa, ushna virya and tridoshahara prabhava, and anti-inflammatory activity in arthritis. It also has analgesic and antipyretic activities. Guggulu has laghu ruksha rasa, ushna virya, katuvipaka, and tridoshahara properties. Anti-inflammatory and anti-arthritic activities of guggulu have been proven by various studies. The contents of drug are predominantly having ushna, laghu, ruksha rasa, and tikta-katu rasa, which can act by kapha chedana, ama nirharana, and agni deepana and, hence, become an ideal and effective drug in Amavata. Eranda taila is effective in producing vata sanama by doshanulomana. Gandhaka is a known Rasayana and the effects are explained beautifully in Yogaratnakara Rasayanadikara. Brihat Saindhavadi Taila is a multidiagnostic medicine, and can be used both internally and externally and the ingredients are Saindhava Lavana, Bida Lavana, Souvarchala Lavana, Shreyasi, Rasna, Satapushpa, Yamani, Sarjika, Maricha, Sunthi, Kushta, Ajamoda, Madhuka, Jiraka, Kana, Pushkara, Erandatala, Kanjika and Mastu and is effective in Sandhi Roga, Vataroga, and Kaphaja Roga owing to the ushna, tikshna, vyayayi, and sukshna properties. It can probably act on the joints and remove the srotorodha, thereby, effectively improving the circulation in joints.

**CONCLUSION**

The combination of Simhanada Guggulu and Brihat Saindhavadi Taila is effective, safe, and tolerable in patients with RA. The combination was most effective in reducing the symptoms, such as joint swelling, joint pain, and stiffness of joints without producing any AEs. It can be concluded that this combination of Simhanada Guggulu and Brihat Saindhavadi Taila can provide significant relief in terms of qualitative and symptomatic aspects of RA, if given for a period of 12 weeks, and the effects will be retained for a much longer period also.

**REFERENCES**

हिंदी सारांश
रुमेटोइड आर्थराइटिस (आम्बाट) रोग के प्रबंधन में सिंहनाद गुगुलु एवं बुख़द सैंथैडी तैल का चिकित्सकीय मूल्यांकन - एक प्रत्याशित बदलकृतिय
अवलोकनकारक अध्ययन

वालीपरम्परा सी, दीप, 2संगीता सागीकेर, 3सुनीता, 4लोकिया जीमा, 5अवता चौधरी
6महावत एस. शम्मी, 7मृदुल खंडूकी, 8बनोता यादव, 9प्रीयोप दुआ, 10मोगवल्ली सी. एस. चव
11राजेश राना, 12विमा रिश्वत, 13मार्ली, 14मदन एम. पाई, 15नारायण सिध्दशास

परिचय: रुमेटोइड आर्थराइटिस (आम्बाट) एक स्वत: प्रतिस्पर्धी (आटोइम्यून) व्याधि है जिसमें संधियाँ एवं संधियों
अतिरिक्त उत्पादन में जीवन स्तर होता है इस व्याधि में पाए जाने वाले मुख्य लक्षण इस प्रकार हैं— संधिगूद्ध, संधियों
में लालकाम, संधियों में सूजन के साथ जलकाहट संधियों में बुख़द, शरीरिक कमजोरी एवं बुख़द। ये सभी लक्षण
आयुर्वेद में वर्णित आम्बाट व्याधि में पाए जाने वाले लक्षणों के समान है।

खेती: रुमेटोइड आर्थराइटिस (आम्बाट) से पीड़ित रोगियों में सिंहनाद गुगुलु एवं बुख़द सैंथैडी तैल की चिकित्सकीय
प्रभावकरता और सुधार का आंकलन करना।

सामग्री व विधि: सी.सी.आर.ए.एस के दो परिशोधक केंद्रों पर एक समानता, ऑफर्न लेबल अध्ययन किया गया। इन
दोनों केंद्रों पर विशेष रोगी विभाग से रोगी प्रवास मामलों को पूरा करने वाले 111 रोगियों का अध्ययन हेतु
नामांकन किया गया। विभिन्न रोगियों को 12 सप्ताह तक सिंहनाद गुगुलु क्रम 1.5 ग्राम मात्रा में दिन में 2 बार
गुले गुलता जल से एक बुख़द सैंथैडी तैल दिन में 2 बार बाढ़ प्रयोग हेतु दिया गया। विकल्पाक के वस्तुपाक
मामलों DAS-28, SF-36 एवं शक्तिशाली सूचकांक (स्वास्थ्य स्वास्थ्य मूल्यांकन प्रणाली) में मूल्यांकन (बेसलॉन)
आधारभूत विश्लेषण एवं उसके बाद परिणामों का घटना हर सप्ताह के लिए गया (14वें, 28वें, 42वें, 56वें, 70वें
एवं 84वें)। गुणमूल्य नमूना दो —परिणाम (paired sample t & test) की उपयोग, परिणामों को मापने हेतु किया गया।

परिणाम: 12वें सप्ताह के अन्त में रोगियों के नैदानिक/लक्षण संभित इकाई तथा DAS-28, SF-36 में महत्वपूर्ण
परिवर्तन/सुधार पाया गया। अध्ययन के दौरान किसी भी प्रकार के प्रतिकूल प्रभाव नहीं पाये गये।

निष्कर्ष: बुख़द सैंथैडी तैल एवं सिंहनाद गुगुलु जब एक साथ बनाए गई मात्रा में आम्बाट (KA) से प्रतिस्थित रोगियों
में दिये गये तो वे अच्छी, सुधारित एवं निरपेक्ष पाये गये।