Lumbar disc herniation with radiculopathy: Study protocol of a randomized controlled clinical trial evaluating the efficacy of Ayurveda treatment protocol.

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Abstract

Background: The single leading cause of disability worldwide is low back pain. The incidence of herniated disc is about 5-20 cases per 1000 adults per year and is prevalent in people in their third to fifth decade of life, with a male-to-female ratio of 2:1. In Ayurveda, disease Grudhrasi simulates radiculopathy. In modern medicine, the first line of treatment includes conservative management including patient education, manual therapy, and non-steroidal anti-inflammatory drugs (NSAIDs). Ayurveda treatment are used to manage lumbar radiculopathy.

Objective: This clinical study aims to compare the safety and efficacy of Ayurveda treatment protocol with standard care in lumbar disc herniation with radiculopathy

Methods: This is an open-labelled, randomized, controlled parallel group clinical trial with sample size of 80 participants to be randomly allocated into two groups. The intervention group receive Ayurveda treatment protocol and the control group will be treated with standard modern care including physiotherapy for a period of 60 days. The changes in Numeric pain assessment scale - VAS score and ODI (Oswestry disability index Version 2.0) score will be taken as the primary outcome measures and will be recorded at baseline (1st day), 8th day (after completing IP treatment), 30th day, and 60th day. The secondary outcome quality of life will be recorded at baseline (1st day), 8th day (after completing IP treatment), 30th day, and 60th day, occurrence of adverse events and need of rescue analgesic medications will be taken as other secondary outcome measures and will be recorded at 8th day (after completing IP treatment), 30th day, and 60th day.

Results: The project was funded in March 2023, and the study period is 36 months. The participant enrollment was started on November 2023. As of May 2025, 58 participants completed the study. The data analysis will be completed by March 2026, and the results are expected to be published by May 2026.

Conclusions: Lumbar disc herniation with radiculopathy affects the quality of life in patients. Ayurveda offers sustainable relief for lumbar disc herniation with radiculopathy. This study will provide scientific evidence on the safety and efficacy of Ayurveda treatment protocol in lumbar disc herniation with radiculopathy Clinical Trial: Clinical Trial Registry of India (CTRI) (CTRI/2023/05/052859).

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ABSTRACT

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Trial Registration: Clinical Trial Registry of India (CTRI) (CTRI/2023/05/052859).

Key words: Ayurveda treatment protocol, lumbar disc herniation, radiculopathy, pelvic traction, conservative management.

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Introduction

The single leading cause of disability worldwide is low back pain; 60-80 % of adults experience low back pain in varying degrees. Even though the etiology and pathology are complex, they are strongly associated with intervertebral disc degeneration (1) (2). The incidence of herniated disc is about 5-20 cases per 1000 adults per year and is prevalent in people in their third to fifth decade of life, with a male-to-female ratio of 2:1(3) (4). About 40% of low back pain is of radicular origin and comes under the umbrella of sciatic syndrome (5). Comprehensive Ayurveda textbooks mention a disease called Grudhrasi which is one among the 80 types of disorders developing due to vitiated Vata (the regulatory functional factor of the body responsible for movement and cognition). The disease name represents the typical gait of the patient which resembles the bird vulture (Grudham) where the leg becomes tense and curved. Grudhrasi has been mentioned as two types Vata dosha predominant and Vata-Kapha dosha predominant. The main symptom of Grudhrasi is pain that starts from the gluteal region (Sphik), and then radiates to down the back, upper back, thigh, knee, calf muscles, and feet in order along with stiffness, pricking pain, and twitching and causes restricted movement of the leg. In the lower back, upper back, thigh, knee, calf muscles, and feet in order, along with these symptoms, aversion to food, feeling of drowsiness, and feeling of heaviness are found additionally (6, 7,8,9).

As per Ayurveda, Basti (medicated enema) is the prime treatment modality for disorders due to vitiated Vata dosha. In this, ingredients are blended into an emulsion and administered through the anorectal route. It has a multidimensional action. (10). Among the different types of Basti, *Madhutailika* Basti regulates the vitiated Vata dosha on its site and balances other doshas, mainly Kapha dosha (11) (Table 1). Rasnasaptakam Kwath is a polyherbal formulation that contains eight medicinal plants viz. *Pulchea lanceolata, Tribulus terrestris, Tinospora cordifolia, Boerhavia diffusa, Ricinus communis, Cedrus deodara, Cassia fistula, and Zingiber officinale* (Table 2). It is effective in Grudhrasi as it has specific actions in Jangha (calf), Uru (thighs), Prishta (low back), Trika(sacral region), and Parswa (flanks).VatariGuggulu is an Ayurvedic formulation containing *Terminalia chebula, Terminalia bellerica, Emblica officinalis*, purified Sulpher, purified resin of *Commiphora mukul*, and Castor oil (Table 3). It also has specific indications in sciatica-like conditions (12) (13). Tila taila (Sesame oil) is plant origin oil which is having anti-inflammatory properties. In Ayurveda, it

is considered the best drug to pacify Vata (14). Owing to obtain optimal results in lumbar radiculopathy, in this project Ayurveda treatment protocol combining Madhutailika Basti, local application of sesame oil, oral administration of Rasnasaptakam Kwath, and Vatari Guggulu are selected.

In modern medicine, lumbar radiculopathy is treated with conservative management like physiotherapy, including pelvic traction, epidural steroid injections, and surgery. The first line of treatment includes conservative management including patient education, manual therapy, and non-steroidal anti-inflammatory drugs (NSAIDs). Most of the patients prefer conservative treatment like pelvic traction over surgery because it carries a lower risk of complications and lower costs (15) (16). In Pelvic Traction, the mechanism is to relieve pain by separating the vertebrae and removing the pressure or contact forces from injured tissue, and also to increase peripheral circulation by a massage effect, and reduce muscle spasm (17). In this study, our objectives are to compare Ayurveda treatment protocol with standard care including NSAID (Diclofenac sodium tablet), Gabaneuron tab, local application of Diclofenac gel, and Pelvic traction on pain and functional disability and to evaluate the change in the quality of life of subjects, the need of analgesic medication and to clinical evaluate the safety of Ayurveda treatment protocol compared to standard care in lumbar disc herniation with radiculopathy.

Methods

Study design and Study setting.

The study isanopen label,randomized controlled, parallel group clinical trialconducted at the National Ayurveda Research Institute for Panchakarma (NARIP), Cheruthuruthy, Thrissur District, Kerala, India, The schedule of screening, enrolment, intervention, assessments, and follow-ups visits in the clinical trial is given in Table 1.

Table1. Schedule of screening, enrolment, intervention, assessments, and follow-ups visits in the clinical trial

	Screening	**Base line**	**8th day**	**30th day**	**60th day**
Determine eligibility based on inclusion/ exclusion criteria	√				
Provision of participant information sheet	√				
Informed consent	√				
Recording of ODI score	√	√	√	√	√
Demographic and medical history	√	√			
MRI investigation	√				

Laboratory investigations	√				√
General Physical examination	√				
Clinical examination	√	√	√	√	√
Assessment of subjective parameters		√	√	√	√
Drug compliance assessment			√	√	
Rescue medication assessment			√	√	√
Adverse event assessment			√	√	√

Study participants
Inclusion Criteria

Participants of either gender in the age group of 25-55 years, having Oswestry disability index (ODI) (18) score between 21% -60 %,diagnosed with lumbar disc herniation with radiculopathydue to intervertebral disc herniation confirmed by MRI, who are willing to provide written informed consent prior to participation in the study, and adhere with the study protocol will be included.

Exclusion criteria

The following exclusion criteria will be used for this study: 1- Indication for surgical intervention for disc herniation like severe motor deficit (motor power of lower limbs assessed through Medical Research Council Manual Muscle Testing scale ≤3), severe spinal stenosis; excruciating pain that cannot be managed by conservative treatment, foraminal stenosis, conjoint nerve root, perineural cyst etc. 2 – Patients who have received non pharmacological interventions like physiotherapy, traction, manual therapy, etc. for the management of lumbar disc herniation in last 3 months. 3- History of or evidence of any of the following –Osteoporotic lumbar fracture, presence of inflammatory or infective diseases that affect spinal morphology, such as ankylosing spondylitis, Spondylodiscitis or inflammatory spondylitis, spondylolisthesis, Pott’s spine, Pyriformis syndrome, sacro-iliitis, neural foraminal stenosis. 4 – History of spinal surgery in last 2 years or having epidural fibrosis. 5 – Patients with caudaequina syndrome or neurological deficits such as foot drop limb muscle wasting and bowel/bladder incontinence or non-ambulatory patients with Monoplegia / Paraplegia / Hemiplegia. 6- Evidence or history of spinal trauma or Spinal Malignancy. 6 -Presence of other medical condition presenting with numbness and pain in lower extremities, such as diabetic polyneuropathy and peripheral vascular disease, Motor Neuron Disease, Multiple Sclerosis, Stroke or Cognitive Impairment. 7 – Major coexisting medical condition such as cancer, chronic obstructive pulmonary disease, cardiovascular disease and severe hepatic and renal dysfunction. 8 – Peptic ulcer disease, GI haemorrhage/perforation. 9 – Obesity (BMI greater than or equal to 30 kg/m^2). 10 –

Metallic implants like pace makers, hearing aid implants etc. and other contraindications for MRI. 11 – Any other condition that as per the investigator is contraindicated for the intervention in the study.

Study intervention

The participants of both groups will be admitted to the inpatient department of NARIP. In the intervention group, the participants will be treated with the Ayurveda treatment protocol. In this, the participants will be given Madhutailika Vasti for 7 days. The medical team will do the Abhyanga (therapeutic massage) using Tila taila and fomentation. Followed by this Madhutailika Vasti will be given through the anal route using sterilized equipment. This will be given from baseline to the 7th day. The participant will receive education about therapeutic massage with Tila taila and will be asked to continue till the 30th day. Oral medications Rasna saptakam Kwath, along with 1 gm Shunti Choorna (dried powder of *Zingiber officinale* Roscoe) and 500mg Vatari Guggulu tablet, will be given twice daily for 30 days from baseline.

The ingredients for Madhutailika Vasti and sesame oil for therapeutic massage was manufactured at the Good Manufacturing Practices (GMP)-certified pharmacy at NARIP, and the Rasna saptakam Kwath, Shunti Choorna, and Vatari Guggulu tablet was manufactured by Indian Medicinal Pharmaceutical Corporation Ltd., new Delhi, India, as per the respective standards available in the Ayurveda Pharmacopoeia India (19).

Participants in the control group will be given Physiotherapy- Pelvic traction according to the weight of the patient for 8-9 hours in a continuous or intermittent method based on the severity of pain. Along with this, Gabaneuron tablet 300mg will be given twice daily for 30 days from baseline and Diclofenac gel will be given for external application for 30 days. Diclofenac sodium tablet (50-75 mg) will be given as per the advice of the Co Investigator (modern medicine) or the modern medicine consultant at NARIP for a maximum period of 7 days as per severity of pain, and advised only to consume it if painful episodes occur during the follow-up period. It is also advised to consume Pantoprazole tablet (40mg) whenever Diclofenac sodium tablet is given. The details of interventions in both groups are given in Table 2.

Table 2: The details of interventions in both groups

Groups	Intervention	Dose/time of administration/anupana	Duration
Group A	Rasnasaptakamkwath	96 ml, 45 minutes before food 96 ml, 45 minutes before food / shunti choorna (1 g)	30 days
	Vatariguggulu	500 mg bid along with kwath	30 days

	Abhyanga with luke warm Tila taila followed by fomentation	30 ml/day, 30 minutes daily once	30 days
	Madhutailikavasti (Ref. Su.Chi38/100-101.)	• Makshika-2 prasruta and 1 karsha (approx.200 gm) • Sanidhavalavana-1 karsha (12 gm) • Murchita Tila taila-2 prasruta and 1 karsha (approx. 200 ml) • Satahwakalka- half pala (24 gm) • Eranda moola kashaya- 4 prasruta& 2 karsha (approx.400 ml) and • 1 madanaphala- approx. 6 g	7 days
Group B	Diclofenac sodium tablet	50.75 mg bid a/f with luke warm water	7 days and if painful episodes occur during follow up period.
	Pantoprazole tab.	40 mg (1-0-0) 30 minutes b/f with luke warm water	7 days and while taking diclofenac tab.
	Gabaneuron tab	300 mg bid a/f with lukewarm water	30 days
	Local Application- Diclofenac gel	SOS	30 days
	Physiotherapy- Pelvic traction	Continuous/Intermittent as per severity	7 days

Outcome measures

The changes in Numeric pain assessment scale - VAS score and ODI (Oswestry disability index Version 2.0) score will be taken as the primary outcome measures. The regular assessment of changes in these will be done at baseline (1st day), 8th day (after completing IP treatment), 30th day, and 60th day. The investigators will ask the patients to rate their pain intensity at each visit using a 0-10 Numeric pain assessment scale. The investigators will also record ODI score using Oswestry disability index Version 2.0. Investigators will educate the participants on how to fill out each question.

The secondary outcome measure are assessment of quality of life using short form 36 (SF-36) will be recorded at baseline, 8th day, 30th day and 60th day. Occurrence of adverse events and Need of Rescue analgesic medication if any will be recorded at 8th day, 30th day and 60th day.

Safety outcomes

During each follow-up visit, the investigator will seek information on adverse events (AEs) and will be recorded in the case report form (CRF) and appropriate treatment will be provided. Any serious adverse event that occurs after the study period and is considered to be possibly related to the study treatment will be recorded and reported immediately.

Withdrawal criteria

Participants himself/ herself want to withdraw from the study for any other reason or if there is non-

compliance will be withdrawn from the study. If there is relation of suspected ADR (Adverse drug reaction)/ AE (Adverse event)/ SAE (Serious adverse event) with the trial intervention confirmed by the causality assessment will be withdrawn from the study. During the course, if the subject meets any exclusion criteria (either newly developed or not previously recognized) will also exclude. The reasons for withdrawal will also be recorded in the participant's case record form (CRF).

Sample size

The sample size of this trial is 80. A previously published article reported after treatment mean change of 5 points in the mean Oswestry Disability Index after treatment as compared to baseline in the patients of control group. We hypothesized that in the intervention group the change in ODI score after treatment as compared to baseline will be 10 points. With a standard deviation of 7 points, 31 participants in each group will be needed to detect the difference with 80% power and 95% confidence interval. Adding an attrition rate of 25% the sample size becomes 40. Therefore, a total of 80 patients will be enrolled in the trial (40 in each group).

Recruitment

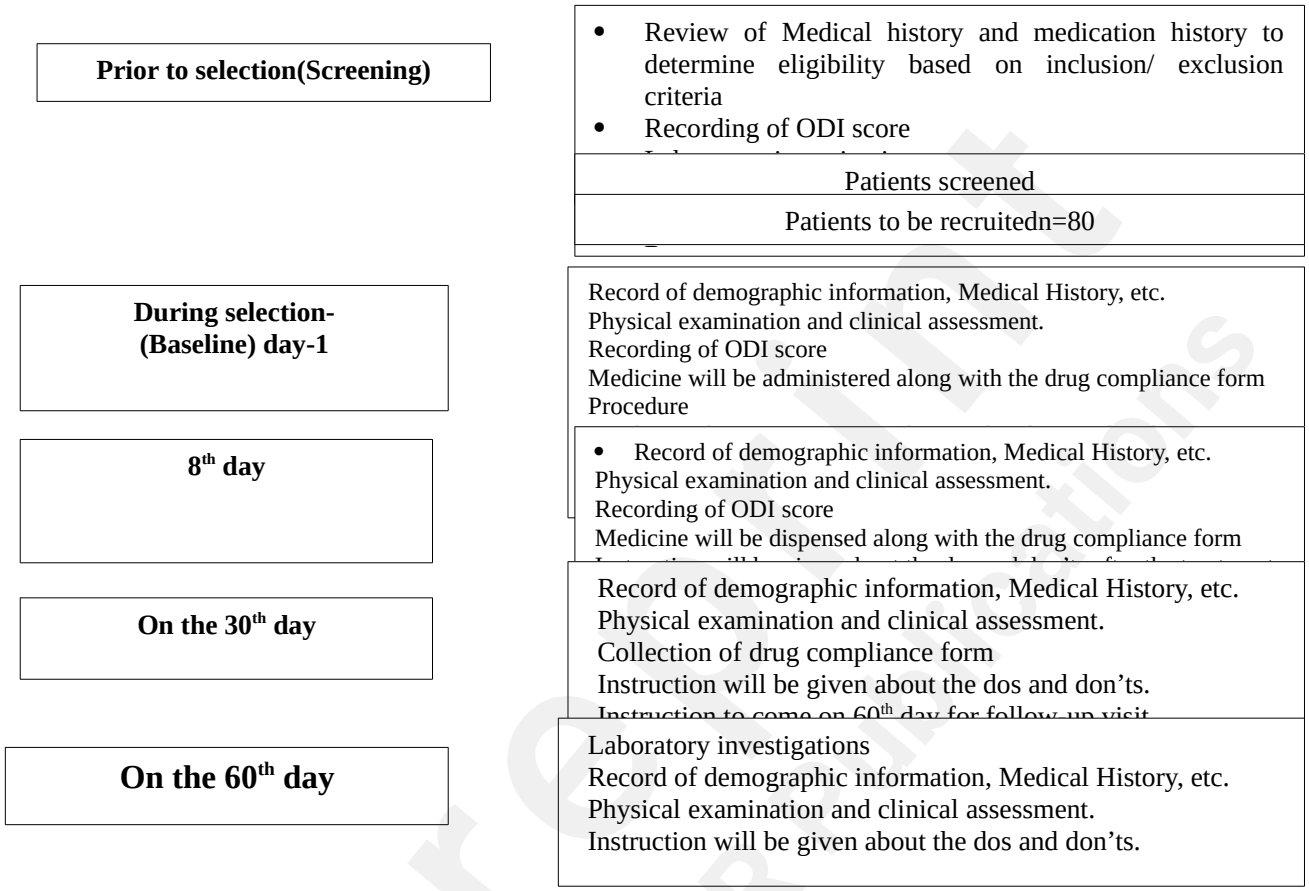
Participants from the outpatient department of NARIP, with features of lumbar radiculopathy will be screened for their eligibility to participate in the clinical trial. The written informed consent of the patients will be obtained before screening. Those subjects having ODI score 21% - 60 % will be subjected to MRI lumbosacral spine for confirmation of the diagnosis. Hemogram, LFT, RFT, CRP, HbA1C, RBS, RA Factor and HLAB27 will be performed at screening. The data will be entered in the CRF for screening and on the 60^{th} day hemogram, LFT, RFT, and CRP will be performed.

Randomization and allocation Concealment

The trial is designed as a single center, open label, randomized, and controlled clinical study. The randomization process of eligible participants into study group or control group will be done by randomized block design method .The process of concealment achieved through SNOSE (sequentially numbered, opaque, sealed envelope). by a third person (statistician) who is not involved in the enrollment of the participants

The details of the study procedure are depicted in Figure 1: Flow chart

Figure 1: Flow chart of Study procedure



Compliance

Compliance assessment form will be issued to the participants to monitor the compliance of prescribed medicines on each visit. The participants will be instructed to complete the assessment form after each administration of medicine. It will be collected during follow up visits.

Concomitant and Rescue Medication

The participants will be asked to inform the investigators about any type of concomitant medication they are taking. The investigators will record the details of such medicines and the reason for taking them in the CRF. If there is any medical emergency, rescue medicines can be used and the details will be recorded in the CRF.

Data Collection and documentation

The investigators and the research team will be trained on Good Clinical Practice (GCP) protocols, trail-specific process, and documentation before commencing the study. The research team will collect information and the details will be filled in the CRF (Figure 1: flow chart). All the

documented data entered by the team will be checked regularly by the Principal Investigator (PI) or Co Investigators (Co I). Any modifications/corrections made will be made clearly visible, and the corrections will be signed and dated by PI or Co I. The data will subsequently enter in an e-format and verified as and when required. The original CRF will be archived.

Statistical Analysis

The Collected data will be checked for its accuracy and completeness. The categorical variables will be reported in number (percentage) and compared through chi-square test between groups. The continuous variables will be represented in Mean±SD or Median (First Quartile, Third Quartile) depending on the distribution of the data. The normality of the data will be checked through probability plot of the data. The groups will be compared through parametric test when data follow normal distribution otherwise non parametric test will be used. The panel data will be analyzed through rANOVA or Generalized Estimating Equation (GEE) depending on the nature of the selected parameters. The level of significance during analysis will be 5%.The data analysis will be performed through STATA/MP 16.1 software.

Monitoring

The sponsor will set up monitoring committee and the committee will conduct virtual monitoring and onsite monitoring to ensure adherence to clinical trial protocol and compliance to GCP and the Central Council for Research in Ayurvedic Sciences Research Policy.

Trial Audit

The regulatory authorities, the institutional ethics committee (IEC), or the funding agency will audit the trial, and the research team will ensure access to all the documents related to the study for the on-site audit.

Ethical Considerations

The IEC of NARIP has been approved the study (F. No. 8/16/23/NARIP/Tech meeting/2509 dated 31 March 2023) and has been registered prospectively at Clinical Trial Registry of India (CTRI) (CTRI/2023/05/052859). The study will be conducted in accordance with the Indian Council for Medical Research National Ethical Guidelines for Biomedical and Health Research on Human participants (2017). Written informed consent (either in English or Malayalam) will be obtained from eligible participants before screening. All protocol modifications will be informed to IEC and funding agency and will be corrected accordingly. The CRFs will be stored in a secure area, and will ensure confidentiality. Routine medical care will be given to study participants, if required, after the completion of study period. The study participants will be compensated with an incidental support of Rs 100 (1.16 US $) for each visit. The study is insured under Clinical Trial Insurance.

Results

The project was funded in March 2023, and the study period is 36 months. The participant enrollment was started on November 2023. As of May 2025, 58 participants completed the study. The data analysis will be completed by March 2026, and the results are expected to be published by May 2026. The outcomes of the study will be disseminated through research articles in peer-reviewed scientific journals and presentations at National conferences.

Discussion

This randomized, open-label clinical trial is expected to assess the effect of Ayurveda treatment protocol compared to standard care in the treatment of lumbar disc herniation with radiculopathy.

Strength

This is the first randomized clinical trial to evaluate the efficacy of Ayurveda treatment protocol in the treatment of lumbar disc herniation with radiculopathy in comparison with standard modern care. The measures used in this clinical trial will yield valid data for the treatment of lumbar disc herniation with radiculopathy.

Limitations

The study is being conducted at a single center, and hence participants from single geographical location may get recruited in the trial. The study is expected to apply to countries where Ayurveda is practiced. However, regulatory permissions to use the Ayurveda treatment protocol and availability of trained persons are essential.

Conclusion

If the clinical trial proves effective, medical professionals can consider Ayurveda treatment protocol as a potential alternative, which may further be incorporated in the management of lumbar disc herniation with radiculopathy to reduce pain and to improve quality of life.

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Authors Contributions

Conceptualization and drafting (original article): APS

Methodological support: PSKM, RKS, LSR, BSS, NS

Writing (review and editing): AA

Protocol and administrative support: BCSR, NS, RA

Conflicts of Interest

None declared

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Table 1

Madhutailika Basti

Sl. No.	**Ingredients**	**Part Used**	**Botanical Name/ English name**	**Family**	**Quantity (For 3 days)**
1	Makshika	-	Honey	-	200 g
2	Saindhava	-	Rock salt	-	12 g
3	Taila	-	-	-	200 ml
4	Kalka-Shatahwa	Seed	*Anethum sowa*Roxb. ex Fleming	Apiaceae	24 g
5	Kwatha - Eranda	Root	*Ricinus communis* L.	Euphorbiaceae	400 ml
6	Madanaphala	Fruit	*Xeromphis spinosa*(Thunb.) Keay	Rubiaceae	6 g

Table 2 Ingredients of Rasnasaptakam Kwath

S. No:	Ingredient	Sanskrit Name	Quantity	Parts used
1.	Pluchea lanceolataOliver &Hiem.	Rasna	1 part	Root
2.	Tinospora cordifolia(Wild) Hook.f&Thomson	Amrita(Guduci)	1 part	Stem
3.	Cassia fistula Linn.	Aragvadha	1 part	Fruir pulp
4.	Cedrus deodara (Roxb.ex D Don) G.Don	Devadaru	1 part	Heart wood
5.	Tribulus terrestris Linn.	Trikantaka(Gokshura)	1 part	Fruit
6.	Ricinus communis Linn.	Eranda	1 part	Root
7.	Boerhavia diffusa Linn.	Punarnava (Rakta Punarnava)	1 part	Root

Table 3 Ingredients of Vatari Guggulu Tablet

Table: ingredients of Vatari Guggulu

S. No	ingredient	Sanskrit Name	Quantity	Parts used
1.	Ricinus communis Linn.	Vatari taila (Eranda)	1 part	seed
2.	Sulfur	Gandhaka- Suddha	1 part	-
3.	Commiphora mukul(Hook. Ex Stocks) Engl.	Pura (Guggulu)-suddha	1 part	Resin
4.	Terminalia chebula Retz.	Haritaki	1 part	Pericarp
5.	Terminalia bellirica(Gaertn) Roxb.	Bibhitaka	1 part	Pericarp
6.	Phyllanthus emblica Linn.	Amalaki	1 part	Pericarp

Supplementary Files

CONSORT (or other) checklists

SPIRIT CHECKLIST.
URL: http://asset.jmir.pub/assets/a1b4cbe3c1e64a11a2888357a4744c55.pdf