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Research Article

A RANDOMIZED CONTROLLED TRIAL TO EVALUATE THE EFFICACY OF *ROHITKYADHYAM CHURNA* AND *PIPPALI GHRITA SNEHAPANA* WITH *AROGYAVARDHINI VATI* AND *TRIPHALA GUGGULU* IN THE MANAGEMENT OF *YAKRIT ROGA* WITH SPECIAL REFERENCE TO METABOLIC DYSFUNCTION-ASSOCIATED STEATOTIC LIVER DISEASE: A STUDY PROTOCOL

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ABSTRACT

Metabolic dysfunction-associated steatoic liver disease (MASLD), previously termed non-alcoholic fatty liver disease, is a growing global health concern associated with obesity, insulin resistance, dyslipidemia, and sedentary lifestyle. The prevalence of Metabolic Dysfunction–Associated Steatotic Liver Disease (MASLD) in India is estimated to be approximately 38.6%, with reported ranges varying from 21.8% to 48.2% in the general population, and rising to 50–80% among individuals with metabolic risk factors such as obesity and type 2 diabetes mellitus. In this study, *Rohitkyadhyam Churna* and *Pippali Ghrita* will be compared with *Arogyavardhini Vati* and *Triphala Guggulu.* **Aim:** To evaluate the efficacy of *Rohitakyadyam Churna* and *Pippali Ghrita Snehapana* with *Arogyavardhini Vati* and *Triphala Guggulu* in the management of *Yakrit Roga* with special reference to MASLD. **Materials and Methods:** A randomized controlled trial will be conducted at Chaudhary Brahm Prakash Ayurved Charak Sansthan from March 2026 to March 2027. 62 participants will be equally divided into two groups. Group A will receive *Rohitkyadhyam Churna* as *Nitya virechan* and *Pippali Ghrita* for *Shamana sneha*, while Group B will receive *Arogyavardhini vati* and *Triphala guggulu*. Assessments will occur at baseline, 15, 30, 45, and 60 days. **Results:** As of March 2026, 62 patients will be enrolled in both groups. Data analysis should be completed by February 2027. The study will be reported in accordance with standard guidelines for randomised controlled trials. Clinical results will be disseminated through conferences and peer-reviewed publications in a relevant journal. **Discussion and Conclusion:** *Rohitakyadyam Churna* and *Pippali Ghrita Snehapana* could be an evidence-based therapeutic tactic for the management of MASLD from an Ayurvedic perspective.

INTRODUCTION

In Ayurveda, the liver is correlated with *Yakrit,* which comprises of two words, *Yaha*, that is, one, and *Krut*, which means does. Thus, the word *Yakrit* stands for an organ that is always active and performing metabolic functions in the body.[1] *Yakrit* exclusively houses *Ranjaka pitta* which governs the formation of red blood cells, and gives color to blood and stool, and 5 *Bhutaagnis*, which are functionally responsible for converting food into biologically useful substances.[2] It is also the root of *Raktavaha Srotas* (channels which are related to the formation and carrying of matured blood) along with *Pleeha. Yakrit Vikāra* refers to disease conditions arising due to vitiation of *Pitta* and *Rakta* along with involvement of *Āma* and *Meda,* leading to functional and structural abnormalities of *Yakrit*[3]. NAFLD can be co-related with *Yakrit Dalyudara* or *Medaja Yakrit Roga* is a *Santarpanajanya Vyadhi* (caused by over nourishment), where the main pathological event is deposition of *Meda* (fat tissue) in *Yakrit.* Initially, the dysfunction of *Agni* leads to the production of *Durmeda*

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(FFA) and *Kleda* which gets localized in the *Yakrit*. Further, it leads to *Yakrit Sopha* (hepatic inflammation) and *Dhatu Rupantara* (Parenchymal change to hepatic stellate cells) after *Dhatu Paka.*[4]

NAFLD is an umbrella term that encompasses a histological spectrum ranging from simple increase in concentration of hepatic triglycerides (TGs), to non-alcoholic steatohepatitis (NASH) characterized by hepatocellular damage, fibrogenesis, subsequently cirrhosis, and cancer[5]. It is a condition where fat accumulation exceeds 5% of the total weight of the liver or more than 30% of liver cells in a liver lobule due to causes other than excessive alcohol use. Risk factors for NAFLD include visceral obesity, hypertension, insulin resistance, and dyslipidemia.[6]

From Ayurveda point of view MASLD may be understood as a disease having complexities of *Yakrit roga* (liver diseases) and *Medoroga* (obesity). It also has a close link to the metabolic syndrome. Sedentary lifestyle, fat rich diet and a higher inherited tendency for metabolic syndromes makes people more prone to NAFLD and NASH[7]. Various mechanisms have been put forth to explain the pathogenesis of the disease. The most widely accepted hypothesis is the development of Hepatic macro steatosis as a result of increases lipolysis and free fatty acids. The increase in the reduction of free fatty acid oxidation with insulin resistance leads to fatty acid accumulation[8].

Need of Study

(MASLD), formerly known as non-alcoholic fatty liver disease, is increasingly prevalent due to sedentary lifestyle, obesity, and metabolic disorders. Currently, there is no definitive pharmacological treatment, and management mainly relies on lifestyle modification. In Ayurveda, MASLD can be correlated with *Yakrit Roga* caused by *Agnimandya, Āma* formation, and *Meda Dushti*. Classical formulations such as and *Pippali Ghrita* along with *Rohitakyadyam Churna*, are traditionally indicated for liver and metabolic disorders. However, strong clinical evidence is limited; therefore, a randomized controlled trial is needed to evaluate their efficacy in the management of MASLD scientifically.

Review of Literature

A dual approach will be used for the literature review: first, a study of foundational Ayurvedic texts (*Brihattrayi, Laghutrayi*, and *Nighantus*) and modern textbooks; and second, a digital screening of indexed databases. Sources including PubMed, Google Scholar, and Scopus will be utilised to identify pertinent journals and research papers, ensuring the study is grounded in both traditional wisdom and current scientific evidence.

Drug Review

Rohitkyadhyam churna[9] Bhaisajya Ratnawali 41/10-11

Pippali ghrita[10] Bhaisajya Ratnawali 41/218

Arogyavardhini vati[11] Rasaratna sammuchya 20/87

Triphala guggulu[12] Sharangdhar Samhita madhyam khand 8/82-83

Source of Data

Patients visiting the Panchakarma OPD and IPD of Chaudhary Brahm Prakash Ayurved Charak Sansthan, Delhi, who meet the inclusion criteria, shall be enrolled in the study after obtaining informed consent.

AIM AND OBJECTIVE

Aim

To evaluate the comparative efficacy of *Rohitkyadhyam churna* and *Pippali ghrita snehapana* with *Arogyavardhini vati* and *Triphala guggulu* in management of *Yakrita roga* (metabolic dysfunction-associated steatoic liver disease).

Objectives

1. To evaluate the efficacy of *Rohitkyadhyam churna* and *Pippali ghrita snehapana* in the management of *Yakrita roga* (metabolic dysfunction-associated steatoic liver disease).
2. To evalauate the efficacy of *Arogyavardhini vati* and *Triphala guggulu* in management of *Yakrit roga* (metabolic dysfunction-associated steatoic liver disease).
3. To compare the efficacy of *Rohitkyadhyam* and *Pippali ghrita snehapana* with *Arogyavardhini vati* and *Triphala Guggulu* in the management of *Yakrit roga* (metabolic dysfunction-associated steatoic liver disease).

Research Question

Whether *Rohitkyadhyam churna* and *Pippali ghrita snehapana* is more effective than *Arogyavardhini vati* and *Triphala guggulu* in the management of *Yakrit roga* (Metabolic dysfunction-associated steatoic liver disease).

Hypothesis

Null Hypothesis: (H0)

Rohitkyadhyam churna and *Pippali ghrita snehapana* is equally effective as *Arogyavardhini vati* and *Triphala guggulu* or less effective in the management of *Yakrita roga* (Metabolic dysfunction-associated steatoic liver disease).

Alternate Hypothesis: (H1)

Rohitkyadhyam churna and *Pippali ghrita snehapana* is more effective than *Arogyavardhini vati* and *Triphala guggulu* in the management of *Yakrit roga.*

Study Design

Type of trial: Interventional

Purpose: Treatment

Masking: Open label

Method of Randomization: SNOSE Randomization

Timing: Prospective

End Point: Efficacy

No. of groups: 2

Subjects: 62 (31 in each group)

Allocation: Selection of patients according to criteria

Phase of trial: Phase 3

Duration of Trial: 12 months

Statistical tool: An appropriate tool will be applied

Methodology

The study will be conducted at Chaudhary Brahm Prakash Ayurved Charak Sansthan, Delhi, India.

Inclusion criteria

1. Patients with age group more than 18 years and less than 60.
2. Ultrasonographical evidence of fatty liver.
3. Deranged liver function test (AST/ALT ratio <0.8).[13]
4. Patient having at least1 out of 5 cardiometabolic criteria[14]; obesity, diabetes, hypertension, increased triglycerides and low HDL.
5. Subjects who are ready to sign the informed consent.

Exclusion criteria

1. Subjects with alcohol intake 20g-40g /day.
2. Subjects with known cases of other liver diseases such as Viral hepatitis (A, B, C, D&E). Autoimmune hepatitis, Wilson's disease, Alpha1 antitrypsin deficiency, haemochromatosis.
3. Subjects currently participating in any other clinical trial (since last 6 month) and pregnant and lactating women.
4. Subjects with ultrasonographical evidence of cirrhosis or necrosis of liver.
5. Subjects who had major surgery within 2 weeks prior to screening visit.
6. Deranged LFT with ALT/ AST ratio more than 1.

Withdrawal Criteria

1. Subjects not willing to continue.
2. If patient develops any other acute illness during trial period which may hinder the study.
3. If patient develops any adverse side effect.
4. The condition of the patient deteriorates during the trial.

Plan of Study

Table 1: Groups

Group	Group A	Group B
Name of drugs	*Rohitkyadhyam churna + Pippali ghrita shamana snehapana*	*Arogyavardhini vati + Triphala guggulu*
No. of patients	31	31
Durations	30 days	30 days
Dose and timing	*Churna* 5 gm empty stomach *Ghrita* – 10ml 2 times a day	*Arogyavardhini vati* 250mg BD *Triphala guggulu* 250mg BD
Route of administration	Oral	Oral

Strategies to Improve Adherence to the Study Protocol

Medication adherence will be assessed at each follow-up visit (15, 30, 45 and 60) by assessing the approximate quantity consumed. The participant will be asked to return the empty medicine container at each follow-up visit. Repeated phone reminders to regularly take medicine to the participants or their family members.

Statistical Analysis

The observations and results will be analysed and presented on the basis of respective and applicable statistics.

Time Duration till Follow-up

In both groups, initially 30 days of treatment and a follow-up period of 60 day.

Criteria for Assessment

Assessment of symptoms[15]

Aruchi (anorexia), *Utklesha* (nausea), *Udarashula* (abdominal pain), *Hridkanthdaha* (epigastric discomfort)

Table 2: *Aruchi*

S.No	Criteria	Score
1.	Absent	0
2.	Willing for food of any two tastes (*Dwirasatmaka*)	1
3.	Willing for food of only one taste (*Ekrasatamaka*	2
4.	No willing for food of any taste	3

Table 3: *Utklesha*

S.No	Criteria	Score
1.	No salivation	0
2.	Occasionally, but not daily	1
3.	After taking food	2
4.	Frequently all day	3

Table 4: *Udarashula*

S.No	Criteria	Score
1.	Absent	0
2.	Presence of *Shula* occasionally	1
3.	Presence of *Shula* after taking food	2
4.	Presence of *Shula* all the time	3

Table 5: *Hridkanthdaha*

S.No	Criteria	Score
1.	Absent	0
2.	Presence of *Daha* occasionally	1
3.	Presence of *Daha* after taking food	2
4.	Presence of *Daha* all the time	3

Objective criteria for assessment

1. Anthropometric measurement: Weight, height ratio (body mass index (BMI).

2.Biochemical: Liver function test (Before and after treatment).

3.Radiological: Ultrasonography (USG) of Abdomen (Liver) before and after treatment.

Table 6: Grading for Ultrasound Abdomen[16]

USG Abdomen Findings	Grades
No fatty liver	0
Slight diffuse increase in the fine echoes. Liver appears bright as compared to cortex of kidney. Normal visualization of diaphragm and intra-hepatic vessel borders.	1
Moderate diffuse increase in fine echoes. Slightly impaired visualization of intra-hepatic vessels and diaphragm.	2
Marked increase in the fine echoes. Poor or no visualization of intra- hepatic vessels borders, diaphragm and the vessels.	3

Primary outcomes: Improvement in the grading of fatty liver.

Data Management: Data coding will be done by the Principal Investigators.

Statistical Methods: Unpaired and Paired t-test.

Consent: Subjects will be given detail information regarding their treatment in Hindi and English. Written consent will be taken from patients before starting the study.

Approval: Approved by IEC, IRC of the concerned University. Trial is registered under Clinical Trials Registry, India.[17]

Dissemination Policy: Will be in the form of paper publication and presentation.

Strengths: If the proposed study results in a positive outcome, then it will establish a new mode of management for MASLD.

RESULTS

Results of the treatment will be tabulated and analysed statistically with relevant tests, and the level of significance will be reported.

DISCUSSION AND CONCLUSION

The conclusion will be mentioned after analysing the data.

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