



## A Protocol Of Assessing *Medodushti* With Special Reference To Nonalcoholic Fatty Liver Disease

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**Abstract:** Nonalcoholic fatty liver disease (NAFLD) is emerging as an important cause of liver disease in India. Epidemiological studies suggest prevalence of NAFLD in around 9-32% of general population in India with higher prevalence in those with overweight or obesity and those with diabetes or prediabetes which can be correlated with Medodushti. Over the past couple of decades , it has become increasingly clear that Nonalcoholic Fatty Liver disease (NAFLD) and nonalcoholic steatohepatitis (NASH) are the significant causes of liver disease.In Ayurveda, NAFLD may be understood as Medodushti. A vast spectrum of diseases comes under Medodushti ranging from Obesity, Hyperlipidaemia, Diabetes Mellitus. According to Charakacharya, Avyama (no exercise), Divaswapna (sleep at day / excessive sleep), Snigdha, Guru , Shita Medya (food which increases lipids), Atimadya sevan (excessive alcohol consumption) leads to Dhatwagnimandya specially Medodhatwagnimandya which may lead to Medodushti. Vitiation of Medovaha strotas takes place in Medodushti or Medorog. The formation of Medodhatu from Mansa dhatu when acted

upon by Meda Dhatwagni on Medopachak Amansha. If any disturbance found in these above pathways during formation of Medodhatu, it may lead to Medodushti i.e. either Vruddhi or Kshya (increase or decrease) of the Medodhatu. NAFLD is a metabolic disorder of hepatic origin. Thus, the treatment of NAFLD should be directed toward normalization of liver functions as well as to the reduction of Insulin resistance. Study Design is randomized controlled clinical study, Study Type is Interventional study Sample size is 134 Subjects (67 in each group) Sample selection techniques: Selections of subjects will be done by computer generated randomization list. Subjects in the age group of 30-65 years of irrespective sex having cardinal features of *Medodushti* pain in the Right upper quadrant/ epigastric region of the abdomen, feeling of nausea and vomiting, loss of appetite, burning sensation in the abdomen and clinical sign and symptoms suggesting NAFLD. • Criteria for Selection of Subjects: Subjects with signs and symptoms suggesting NAFLD will be selected from OPD Department of Kayachikitsa (MAM's Sumatibhai Shah Ayurved Mahavidyalaya, Pune & PDEA's College of Ayurved & Research centre, Nigdi Pune). Approval of the study will be taken after presentation from institute's ethics committee. The cases will be enrolled after describing the treatment and obtaining informed consent in English and local language. Subjects eligible for inclusion criterion who will be selected for clinical trial, drugs are Standardized and well authenticated & will be procured from market. Interventional trial will be measured and by proper statistical analysis the observations of parameters are assessed.

**Keywords:** Medodushti, Nonalcoholic Fatty Liver disease, Medodhatu, Medovruddhi, Medodhatwagnimandya

## 1. Introduction:

Global prevalence of Nonalcoholic fatty liver disease is 25.24% with highest prevalence in the Middle East and South America and lowest in Africa<sup>[1]</sup> Formerly named nonalcoholic fatty liver disease (NAFLD), the spectrum of fatty liver disorders not resulting from alcohol abuse, viral, autoimmune, drug-induced and genetic etiologies, has recently been renamed metabolic (dysfunction) associated fatty liver disease (MAFLD).<sup>[2]</sup> Liver diseases are fast growing and being recognized as public health priorities in India. The prevalence of Fatty Liver of Alcohol(ALD) and Non-Alcohol (NAFLD) are above the burden of viral hepatitis. Although a National NAFLD control program has just been launched in 2021 that integrate liver disease control more broadly into another non communicable diseases control program.<sup>[3]</sup> NAFLD associated HCC is increasing which occurred in the absence of cirrhosis. It is commonly associated with Metabolic Syndrome, obesity, diabetes, and hyperlipidemia. This fatty liver also associated with High blood pressure, Kidney diseases, and heart diseases.<sup>[4]</sup> Therefore, prevention and arrest the progress of fatty liver in highly required. The holistic concepts of Ayurveda give emphasis to health promotion, disease prevention, early diagnosis and personalized treatment even in Liver care. Various Scholar tried to establish the Ayurveda nomenclature and treatment of liver diseases in scientific approach through evidence based procedures.<sup>[5]</sup> Fatty liver is a metabolic disorders involves hormonal, nutritional, and genetic factor. Gut derived hormones, the adipose derived hormones leptin and adiponectin are suspected to play a vital role in fatty liver. High saturated fat, low fiber and carbohydrate-rich diets have been known as risk diet in Fatty liver. But diet rich in fructose and sucrose are also steatogenesis. The primary sensor of GI tract (Microbata) and diet modulate the gut bacterial composition. Alcohol and some allopathic drug destroy the bacterial compositions. Some genes are identified which are involved in fatty liver independent of obesity and alcohol use.<sup>[6]</sup>

## 2. Fatty Liver: Ayurvedic Prospective

Fatty Liver corresponds to the presence of fat in Liver, which refer as Meda(Fat) in Yakrit( Liver). So recent days authors termed as Medaja Yakrit roga.<sup>[7]</sup> There is a significant increase in size in fatty liver so some authors termed as Kaphaja Yakridalludara.<sup>[8]</sup> It is well known that fatty liver is a spectrum of diseases, so the symptoms resembles with Kaphaja Udararoga, then Pittaja and Tridoja Udara roga. Ayurveda Scholars established the samprapti (pathophysiology) of medaja Yakrit roga which reveals that Dosha Dhatu and Mala as basic component of body and their balanced and imbalanced state of are known as health and disease respectively. Vata, Pitta and Kapha are three humors (Tridosha) which functional aspect of living things. Dhatus are seven in number which are structural entity of body. Malas (Body waste) are waste product of Ahara (diet) and Dhatu and their proper excretion is very vital for homeostasis. Dhatvagni Paka (component

responsible for tissue metabolism) is a process in which convert the Dhatu to Poshakadhatu (immobile and storage part) and Poshya Dhatu (mobile part). This Poshya Dhatu which is the movable part circulate in its own Srotas for the nutrition of successive Dhatu whereas Poshaka part act as storage and in emergence condition can be utilized as Poshya Dhatu. Again Bhutagni Paka carried out inside the cell for various nutrients utilised for cellular function. They maintained homeostasis in the principle of Svabhava Satmya (immunity), Samanya and Vishesha (theory of homologous and analogous). The Bio energy (Bala) is important aspect in Ayurveda for the pathogenesis of any diseases. It provides strength to all Dhatu, protect them and Kostanga (organ) from Krimi (Infection) and Aghata (injury) and provide stability of different organ. It works as immune surveillance and maintain homeostasis. Dhatu Paka is a condition of suppuration or destruction of Dhatu due to excess Agni (heat) or Srotarodha (Block of passage) or Kshaya (malnutrition). The cardinal sign of Dhatupaka are Nidranasha (sleeplessness), Hrudistambha (heaviness / discomfort of chest), Vistabha (constipation), Gaurabha (heaviness of body), Aruchi (Anorexia), Arati (Anxiety or dullness) and Balahani (Loss of strength/immunity). *Dhatu Rupantara* (Change of architecture of tissues) is a stage where one Dhatu is changed to another Dhatu, Upadhatu or Mala, example - Mamsa Dhatu changed to Meda Dhatu or Mamsa Dhatu changed to Kandara. Meda is the fourth Dhatu as per Ayurveda doctrine and resemble with the adipose tissue. If the Meda Dhatvagni (Digestive power/ adipokines) deregulated than there is a disharmony of distribution of Baddha Meda (store in particular site) and Abaddha Meda (circulating fat). This Baddha Meda can be termed as Visceral fat and Abaddha Meda can be understood as circulating lipids. Durmeda is another term found in Ayurvedic literature which is nothing but Ama of Meda. Durmeda can be understood as free fatty acid. Excess Abadhha Meda / Durmeda are responsible for accumulation in any Dhatu, Srotas, Kostanga, Sira, Granthi etc. and form Gara Visha (lipotoxicity) and disease process initiated. Meda Dhatu is nourished from Sneha (fatty food) as per Madhava Nidana. Its distribution in Mamsa Dhatu as Vasa (subcutaneous fat) Updhatu and in small bones as Sarakta Meda (red bone marrow). The different components of Meda and their function are described and found all are directly or indirectly responsible for Yakrit Roga. Form this phenomena it can be concluded that Meda can create not only as Sthyaulya (Obesity) but also organ specific disorders like – Medaja Granthi, Medaja Masurika, Medaja Galaganda, Medaja Vridhi etc. But Medaja Yakritdalludara or Yakrit Vikara is not enumerated in classical Ayurvedic literature. Strong evidence suggested that accumulation of lipids in nonadipose tissues can contribute to cellular dysfunction and cell death, a phenomenon that is called lipotoxicity. Like that due to hypo function of Jatharagni and Medodhatwagni leads to more production of Abaddha Meda and Durmeda leading to accumulation in all Srotas including Raktavaha, Mamsavaha and Medovaha Srotas. Sneha Guna in liver will increase due to accumulation of Meda as Pitta and Meda have Sneha Guna. Therefore there is deregulation of Pitta production as triggered by Sneha Guna. Another events are that more Kleda production is initiated due to reduced Ushna and more influx of Rasadhatu. Pitta is not excreted out properly due to Srotorodha (obstruction of channels). This primary situation leads to accumulation

of Durmeda in Yakrit known as Medaja Yakrit Dalludara (fatty liver). The further development of the disease involves function of Jatharagni, Dhatvagni, Bhutagni, Durmeda Visha (endotoxins and lipotoxicity), Sthyaulya (obesity) and Kapha Prakruiti (genetic predispositions) for Dhatu Paka (necrosis of hepatocyte) and Dhatu Rupantara (Fibrosis). As Yakrit is chief organ of Raktavaha Srotas and intake of the Vidahi, Snigdha and Ushna Annapaana along with exposure to excessive sunlight and air lead to Raktavaha Srotodushti. Again it exposed to various threats of Krimi (infection) as it is a Raktakshaya and various nutrients of Ahara Rasa as literature supports that Ahara Rasa is first received by Jyotisthana (Liver) which further nourishes the whole body. Therefore Bala (Immunity) played a key role in the pathogenesis of Yakrit Vikara. The Bala of different components of Meda, its Bhautic compositions and its strength are stated. As Meda and Prakruita Kapha are same and similar properties, so they have definite role in formation of Bala. It is also found that tissue resident macrophages are serving as immune sentinels and they interact with parenchyma cells to boost immunologic well being. Adipokine released from fat cells have a definite role on regulatory T cell population, hypertrophy and hyperplasia of adipose tissue. Central Council for Research in Ayurveda Sciences established dedicated Institute for Hepatobiliary disorders at Bhubaneswar, Odisha for more fundamental and clinical research. Ayurveda. It has entered a Memorandum of Understanding (MoUs) with JawaharLal Nehru University (JNU) and Institute of Liver and Biliary Sciences (ILBS) for more research in liver. The recent inauguration of WHO Global center for Traditional medicine at Jamnagar, India will hardness the safety and efficacy of Ayurveda in wellness, prevention, promotion and treatment.

## Need of Study:

India is the seventh largest and second most populous country in the world. It has a rapidly developing economy with an estimated gross domestic product of US \$2.87 trillion. Easy access to calorie-dense food and sedentary lifestyle together with the modern epidemics of diabetes mellitus (DM) and obesity have catapulted nonalcoholic fatty liver disease (NAFLD) into a substantial public health problem in India as in other parts of the world. NAFLD has emerged as one of the leading causes of cirrhosis, hepatocellular carcinoma (HCC), and liver transplant in India.<sup>[9]</sup> Given its enormous population, the burden of NAFLD in India is likely to be substantial, which may significantly impact the limited health care resources in the country.

No established pharmacological treatment available for Nonalcoholic Fatty Liver Disease in Modern medicine. Its treatment is still evolving, with no single drug clearly shown to be effective. Dietary modifications is used as treatment but effective in very few patients. There is no work done on Phalatrikadi guggul and tablet Rosuvastatin in Medodushti, so these drugs and disease combination is selected.

**Aim :** To study the efficacy of *Phalatrikadi guggul* with tablet Rosuvastatin in *Medodushti* with special reference to Nonalcoholic Fatty Liver Disease.

## Objectives :

### Primary Objectives :-

1. To compare the efficacy of Phalatrikadi guggul with tablet Rosuvastatin for 2 months in Medodushti with special reference to Nonalcoholic Fatty Liver Disease.
2. Assessment of efficacy of Phalatrikadi guggul in Nonalcoholic Fatty Liver Disease related Parameters i.e.Comparative assessment of changes in fatty liver stage (using Ultrasonography) between two groups.

### Secondary Objectives :

1. Comparative assessment of change in Liver functions [AST, ALT, serum total bilirubin, serum direct and indirect bilirubin, serum alkaline phosphatase, serum gamma-glutamyl transferase (GGT), serum protein, serum albumin and serum globulin] [Inclusion Day , Day 30 and Day 60 ] between two groups.
2. Comparative assessment of changes in serum total cholesterol, Low density lipoprotein (LDL) cholesterol, High density lipoprotein (HDL) cholesterol, Triglycerides (TG), Very low-density lipoprotein (VLDL), TC/HDL ratio, LDL/HDL ratio (before and after treatment) between two groups
3. Comparative assessment of fasting serum insulin (before and after treatment) between two groups
4. Comparative assessment of weight and BMI over two months between two groups
5. Global assessment for overall change by the subject and investigator at the end of study treatment between two groups

## Material and Methods:

**Materials Participants:** Subjects with Nonalcoholic Fatty Liver Disease will be randomly selected from the OPD and IPD of Hospital.

**Safety Assessments:**

Assessment of tolerability of study drugs by assessing ADRs, vitals and clinical symptoms on study completion

**Test drug : Phalatrikadi guggul<sup>[10]</sup>**

Drug	Latin name	Family	Upayuktanga	Quantity
Guduchi <sup>[11]</sup>	<i>Tinospora cardifolia</i>	Menispermaceae	Panchang	1/4 <sup>th</sup> Bhagh
Vasa <sup>[12]</sup>	<i>Adhatoda vasaka</i>	Acanthaceae	Patra	1/4 <sup>th</sup> Bhagh
Kalmegha <sup>[13]</sup>	<i>Andrographis paniculata</i>	Acanthaceae	Panchang	1 Bhagh
Amalaki <sup>[14]</sup>	<i>Emblica officinalis</i>	Phyllanthaceae	Phala	1 Bhagh
Haritaki <sup>[15]</sup>	<i>Terminalia chebula</i>	Combretaceae	Phala	1 Bhagh
Bibhitaki <sup>[16]</sup>	<i>Terminalia Bellirica</i>	Combretaceae	Phala	1 Bhagh
Nimba <sup>[17]</sup>	<i>Azadirachta indica</i>	Meliaceae	Twak	1 Bhagh
Kutaki <sup>[18]</sup>	<i>Picrorhiza kurroa</i>	Plantaginaceae	Root	1 Bhagh
Guggul <sup>[19]</sup>	<i>Commiphora mukul</i>	Burseraceae	Resin	3 Bhagh

Table 1: Phalatrikadi guggul dravya.

**Treatment Protocol:**

Drug	Test drug Phalatrikadi Guggul	Standard drug Rosuvastatin
No. Of patients	67	67
Matra	500 mg	10 mg
Kaal	Two times a day before Meal	Once in a day after meal
Anupan	Water	Water
Duration	60 days	60 days

Table 2: Treatment Protocol

## Methodology

**Study design:** Randomized Controlled Clinical study.

**Type of study:** Prospective Interventional study

**Study Area:** OPD/IPD of College hospital.

**Study Duration:** 1.5 years.

**Sample size:** 67 patients in each group.

### Sample Size calculation:

Prevalence of Nonalcoholic Fatty Liver Disease is 9-32% average is taken 20%. As per prevalence sample size per group considering 10% dropout will be –

$$n = Z^2 \times P (1-P) / d^2$$

Z = standard normal variable P = prevalence

d = error

$$n = (1.96)^2 \times 0.2 \times 0.8 / (0.1)^2$$

$$n = 61.46 \text{ i.e. } 61$$

$$10\% \text{ dropout} = 61 + 6 = 67$$

### Sampling Technique:

Eligible and willing patients will be allocated in two groups by Computer generated random number table from patients in OPD/IPD and till the desired sample size achieved. Patients of Nonalcoholic fatty liver disease will be selected in OPD/IPD on the basis of irrespective of gender, economic status, religion, and occupation. Assessment will be done pre-post Treatment follow-up and data collection will be done on 1<sup>st</sup>, 30<sup>th</sup>, 60<sup>th</sup> day of treatment. Treatment will be given to patients as it mentioned previously and their efficacy will be seen.

### Case Definition:

### Medovaha Strotodushti :

Vitiation of Medovaha strotas takes place in Medodushti or Medorog. The formation of Medo dhatu is from Mamsa dhatu when acted upon by Meda-dhatwagni on Medoposhak amansha. If any disturbance found in these above pathways during formation of Medodhatu, it may lead to Medodushti i.e. either Vruddhi or Kshaya ( increase or decrease ) of the Medodhatu.<sup>[20]</sup>

### Probable Mode of Action

Medicinal Plant	Bioactive molecule	Pharmacological effect on liver
<i>Picrorhiza kurroa (Katuki)</i>	Kutkoside, Picroliva	liver protective, anti-cancer
<i>Tinospora cordifolia (guduchi)</i>	Diterpenoid Lactones, Glycosides, Steroids, Sesquiterpenoid, Phenolics	Anti-fibrotic, anti-tumor, Immuno modulator, excess can induce liver injury
<i>Adhatoda zeylanica Medicus</i>	Alkaloids- Quinazoline, Flavonoids, Tannins, Vasicinone, Essential oil Alkaloids- Quinazoline, Flavonoids, Tannins, Vasicinone, Essential oil Alkaloids-	Hepatoprotective activity, Anti-inflammatory activity, Anticancer activity, Antioxidant activity,

	Quinazoline, Flavonoids, Tannins, Vasicinone, Essential oil	
<i>Andrographis paniculata Burm.f.</i>	Terpenoid lactones and flavonoids	Anti-inflammatory, analgesic, anticancer, antidiabetic, antifertility,
<i>Embllica officinalis Garrtn.</i>	Gallic acid, gallotannin, ellagic acid and corilagin	Hepatoprotective, Antioxidant, Hypolipidemic, Cardioprotective
<i>Terminalia chebula.Retz.</i>	flavonoids, tannins, phenolic acids	Antioxidant, hepatoprotective, neuroprotective, cytotoxic, antidiabetic, anti-inflammatory activities
<i>Terminalia bellirica Roxb</i>	beta-sitosterol, gallic acid, ellagic acid, ethyl gallate, galloyl glucose, chebulagic acid	Antioxidant, Hepatoprotective, Antimicrobial, Antidiabetic, Antithrombotic and thrombolytic.
<i>Azadirachta Indica A. Juss</i>	Azadirachtin, Salannin, Meliantriol, and Nimbin	Antioxidant, Antidiabetic, Antibacterial
<i>Commiphora mukul Engl.</i>	E-guggulsterones and Z-guggulsterones, Myrrhanol-A Cambranoids, Ellagic acid, eugenol, ellagic acid, quercetin, campesterol and campesterol.	antioxidant, anti-inflammatory and antimicrobial, anti-hypercholesterolemic, anti-hyperlipidemic, anti-hypothyroidism, anti-obesity, anti-osteoarthritic

### Inclusion criteria :

1. Gender – Irrespective of gender.
2. Age – 30 to 65 years.
3. Nonalcoholics, or history of alcohol intake less than 20gm/day (history of alcohol intake will be taken separately obtained from the patient and close relatives).
4. Clinical sign and symptoms suggesting NAFLD / Medodushti, i.e. pain in the Right upper quadrant/ epigastric region of the abdomen, feeling of nausea and vomiting, loss of appetite, burning sensation in the abdomen.
5. No complaints – incidental finding during investigations for some other disease.
6. Ultrasonography (USG) abdomen suggestive of NAFLD.
7. Biochemical : Liver function tests showing raised alanine transaminases (ALT) or aspartate transaminases (AST) levels raised above the normal limits (40 IU/L up to 300 IU/L) and with or without raised lipid profile.
8. HbA1c < 9 gm/dl.
9. BMI < 40.

### Exclusion Criteria :

1. Patients with a H/O alcohol intake exceeding 20g/d (history of alcohol consumption history shall be separately obtained from the patient and close relatives)
2. Patients testing positive for markers of other Viral Hepatitis.
3. Pregnant women, Lactating mother.
4. Patient suffering from Alcoholic Fatty Liver Disease and Nonalcoholic Steatohepatitis (NASH).
5. Patients with complications of Nonalcoholic Fatty Liver Disease like Cardiovascular and Renal complications.
6. Patients having Cholecystitis, Pancreatitis or any acute inflammatory condition.
7. Patients having Uncontrolled DM (HbA1c > 9).
8. Patients having major systemic illness like CA, Renal failure, HIV, IHD, Cirrhosis of Liver, Severe anaemia (Hb < 7gm%).

9. BMI > 40
10. Patients participating / participated in another clinical drug study within 3 months before recruitment.

**Withdrawal criteria :** the patients will be withdrawn from the test if –

1. If the patient is not willing to follow assessment schedule of trial.
2. Patients will be withdrawn from intervention if any harmful incidence, signs of drug allergy, or any problem will occur.
3. The physician consultation and appropriate treatment will be provided to the subject having any adverse effect or emergency for any symptom causing deterioration in health.

### **Other Work**

- Preparation of case record form.
- Selection of study subjects.
- Written consent of patient will be taken priorly.
- Administration of drug for 60 days.

### **Standard operating procedure :**

According to scientific method of preparation, mentioned in Sharangdhar Samhita madhyam Khand. <sup>[21]</sup> *phalatrikadi guggul vati* will be prepared weighing 500 mg each for easy administration and for patient convenience.

#### **Collection :**

All drugs will be purchased from local market.

It will be authenticate from authentic Laboratory

#### **PROCEDURE :**

All the crude drugs in given quantity will be reduced to a coarse powder form. Prepared mixture is obtained. Bharad of above drugs also be taken, 16 times water will be added and 1/4<sup>th</sup> of quatha will be obtained and given bhavna of this quatha to above powder.

Guggul will be added to above and granules will be prepared and vati of 500 mg each will be prepared from it in Rotatory Tablet Machine.

#### **METHODOLOGY FOR STANDARDIZATION :**

The Standardization will be done for following parameters –

Raw material

In process

Finished product

#### **Analytical study :**

The Standardization of vati will be done for following parameters – Average weight

Average diameter Average hardness Disintegration time Friability

Microscopic study

All Raw materials used in trial in crude form will be collected from genuine source. They Will be Authenticated and standardized.

## Preparation of Drug

Preparation of Phalatrikadi vati will be prepared is done in attached pharmacy.

## Study Plan

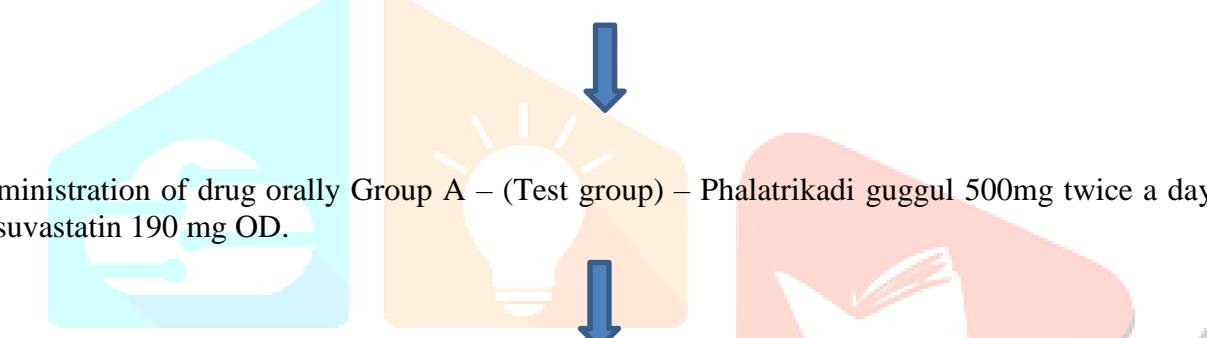
Standard control clinical study



Selection of patients as per Inclusion criteria



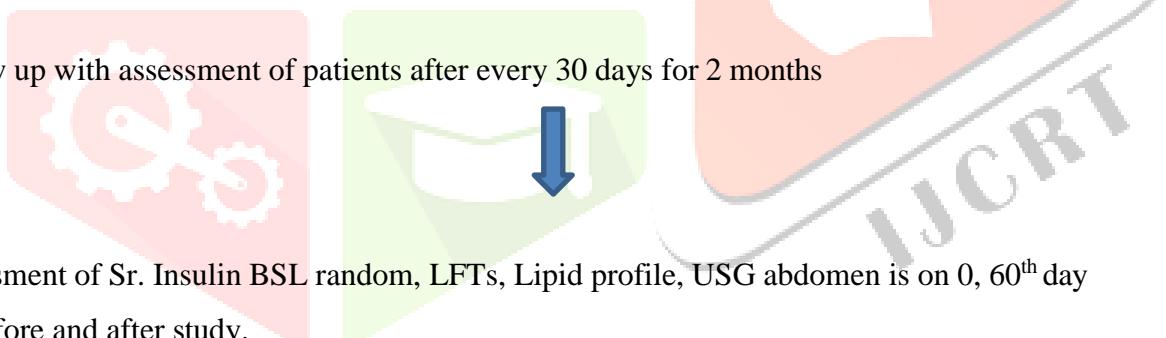
Initial Assessment and Enrolment



Administration of drug orally Group A – (Test group) – Phalatrikadi guggul 500mg twice a day, Group B – Rosuvastatin 190 mg OD.



Follow up with assessment of patients after every 30 days for 2 months



Assessment of Sr. Insulin BSL random, LFTs, Lipid profile, USG abdomen is on 0, 60<sup>th</sup> day i.e. before and after study.



Data collection and Systemization.



Statistical analysis and interpretation of result.



Conclusion will be drawn on the basis of statistical analysis.

## Assessment Criteria

### Parameters for Subjective Criteria

1. Udershool (Pain in abdomen)
2. Utklesh (feeling of nausea and vomitting)
3. Agnimandya (loss of appetite)
4. Klama (tiredness)
5. Adhman (distension of abdomen)
6. No complaints

### Objective Criteria :

1. Biochemical tests : Lipid profile, LFTs, Sr. Insulin, BSL random.
2. Radiological : USG abdomen

### Statistical Methods

With proper s Statistical analysis:

1. Paired T test
2. ANOVA test
3. Wilcoxon test
4. Friedman test. Appropriate test will be added time to time.

### Observation and Results

#### Assessment of Results

The effect of *Phalatrikadi guggul* in two groups (results) will be assessed regarding the clinical signs and symptoms. All subjective and objective parameters will be observed and recorded as before Treatment (BT) and after Treatment (AT) then the comparison of groups will be done.

- Ethical Consideration: Study will be started after the ethical clearance from IEC.
- Withdrawal Criteria: Patient will be withdrawn from the study if there will be any adverse effect occurs, and then he or she will be treated for the same in free of cost.
- Consent according to ICMR Format: Enclosed and will be taken.
- Information to the Patients: All information about drug will be given to the subject in his/ her language

### Expected Results :

- The Subjects with nonalcoholic fatty liver fit for oral intervention of *Phalatrikadi guggul* and limiting sign and symptoms in NAFLD is expected result will be withdrawn on the basis of observations.
- Prevention and stop the progression of Fatty liver Diseases.

### Outcome

- Ayurveda medication can improve the hepatic lipid metabolism, stop hepatic lipogenesis, regulate the mitochondrial dysfunction, modulate lipid metabolism by bile synthesis, modulate the hepatic inflammation through apoptosis and autophagy, correction of gut bacterial composition.
- Liver directed Ayurveda medication are nothing but Yakrit uttejaka (liver stimulant), Pitta saraka (bile excretion), Sothagna and pittghna( reduce bile production).
- Reliving in sign and symptoms in the subjects intervened.

- Early identification and management of NAFLD which may prove key factor on preventing future lifestyle disorders.
- Fatty liver disease is an increasing condition that may progress to end stage liver disease. It has potential to progress to cirrhosis and liver failure. No established pharmacological treatment is available for fatty liver disease in modern medicine. Its treatment is still evolving, with no single drug clearly shown to be effective. Hence, there is a search for alternative treatment modalities in other systems of medicine, which is safe and cost-effective.

## Discussion

Discussion will be done on the basis of observations and results of groups and comparative statistical Analysis. A number of articles related NAFLD and related conditions available in this region will be reviewed.

## References:

1. <https://pubmed.ncbi.nlm.nih.gov>
2. Eslam, M.; Sanyal, A.J.; George, J. NAFLD: A consensus-driven proposed nomenclature for metabolic-associated fatty liver disease. *Gastroenterology* **2020**. [\[CrossRef\]](#)
3. Kalra S, Vithalani M, Gulati G, Kulkarni CM, Kadam Y, Pallivathukkal J, et al. Study of prevalence of nonalcoholic fatty liver disease (NAFLD) in type 2 diabetes patients in India (SPRINT). *J Assoc Physicians India*. 2013;61(7):448–53.
4. Younossi ZM. Non-alcoholic fatty liver disease - A global public health perspective. *J Hepatol*. 2019;70(3):531–44. doi:10.1016/j.jhep.2018.10.033.
5. Panda AK, Kar A, Gupta N, Yadav R, Mishra G, Rout S. A Consensus driven statement for Ayurvedic Nomenclature of Various liver diseases (Yakrit Roga). . IJATM [Internet]. 2021Dec. *Int J Ayurveda Tradit Med*. 2021;3(5):16–21.
6. Carr RM, Oranu A, Khungar V. Nonalcoholic Fatty Liver Disease: Pathophysiology and Management. *Gastroenterol Clin North Am*. 2016;45(4):639–52.
7. Panda A, Hazra J. Patala Katurohinyadi Kwatha In Kaphaja Yakrit Dalludara (Non-Alcoholic Fatty Liver Disease): A Case Study. *Int J Ayurveda Pharma Res*. 2020;8(11):62–6.
8. Panda AK, Bhuyan KGC, Kanta K, Binitha P, Otta S. Role of Meda (Adipocyte) in Yakrit Vikara (liver diseases) - Ayurveda prospective. *J Ayurveda Integrated Med Sci*. 2020;5(2):141–7.
9. Singh SP, Misra B, Kar SK, et al. Nonalcoholic fatty liver disease (NAFLD) without insulin resistance: Is it different? *Clin Res Hepatol Gastroenterol* 2015;39:482-488. [\[PubMed\]](#) [\[Google Scholar\]](#)
10. Bruhatrayeratna Vaidhyaraj A.V.Datar Pranit Panchabhautik Chikitsa paddhatimadhil Vees Pramukh aushadhi kalpa, Dr. Sudhakar Haladvanekar Dr. Gayatri Bhosekar Pg. no. 28.
11. Mishra B., Bhavprakash Nighantu; bhag 1, Chaukhamba Sanskrit Bhavan- 11<sup>th</sup> edition 2007, Haritkyadi varga- Aamalaki Guduchi, page no. 87,88.
12. Mishra B., Bhavprakash Nighantu; bhag 1, Chaukhamba Sanskrit Bhavan- 11<sup>th</sup> edition 2007, Haritkyadi varga- Vasa, page no 103.
13. Mishra B., Bhavprakash Nighantu; bhag 1, Chaukhamba Sanskrit Bhavan- 11<sup>th</sup> edition 2007, Haritkyadi varga- Kalmegh, page no 35.
14. Mishra B., Bhavprakash Nighantu; bhag 1, Chaukhamba Sanskrit Bhavan- 11<sup>th</sup> edition 2007, Haritkyadi varga- Aamalaki, page no 10,11.
15. ShrimadBhavmishrakrit Bhavprakashnighantu; Pandey Ramtej Shastri, Chaukhamba Surbharti Prakashan – 3<sup>rd</sup> edition 2003, Haritaki - Haritkyadivarga, page no 3.
16. . ShrimadBhavmishrakrit Bhavprakashnighantu; Pandey Ramtej Shastri, Chaukhamba Surbharti Prakashan – 3<sup>rd</sup> edition 2003, Bibhitaki - Haritkyadivarga, page no 6.
17. ShrimadBhavmishrakrit Bhavprakashnighantu; Pandey Ramtej Shastri, Chaukhamba Surbharti Prakashan – 3<sup>rd</sup> edition 2003, Nimba - Guduchyadivarga, page no 104.
18. . ShrimadBhavmishrakrit Bhavprakashnighantu; Pandey Ramtej Shastri, Chaukhamba Surbharti Prakashan –

3<sup>rd</sup> edition 2003, Kutaki - Haritkyadivarga, page no 34.

19. ShrimadBhavmishrakrit Bhavprakashnighantu; Pandey Ramtej Shastri, Chaukhambha Surbharti Prakashan – 3<sup>rd</sup> edition 2003, Guggul - Karpuradivarga, page no 67.

20. Charak sutrasthana 28/12

