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Protocol for an Open Labelled Parallel Comparative Clinical Study to Evaluate the Efficacy of Karkashdaladi Kwath and Navaka Guggulu in the Management of Medodushti with Special Reference to Dyslipidemia

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Abstract: Background: Dyslipidemia can be correlated with Medodushti as described in Ayurveda. It is characterized by abnormal lipid metabolism and is highly prevalent worldwide. Dyslipidemia is one of the major modifiable risk factors for diabetes mellitus, obesity, chronic heart diseases, and thyroid disorders. Although statins are the treatment of choice in modern medicine, their long-term use may be associated with several adverse effects. Therefore, there is a need to explore safe and effective Ayurvedic interventions for its management.

Objective: To evaluate and compare the clinical efficacy of Karkashdaladi Kwath and Navaka Guggulu in the management of Medodushti w.s.r to Dyslipidemia.

Methods: A single-centered, open-labelled, parallel comparative clinical trial will be conducted on 60 patients (aged 25–45 years) diagnosed with Medodushti. Participants will be randomized into two groups (n = 30 each). Group A Karkashdaladi kwath (50ml twice daily) and Group-B), Navaka Guggulu (500 mg twice daily). The treatment will continue for 28 days. Outcome assessments include subjective parameters (dyspnoea, thirst etc.) and objective parameters (T. Cholesterol, triglyceride, LDL etc). Follow-up evaluations on days 7th, 14th, 21st, 28th during treatment and days 42nd and 56th post-treatment. Statistical significance is set at $p < 0.05$.

Expected Results: Both formulations will anticipated to improve clinical indices and biochemical data related to Dyslipidemia in Medodushti patients. However, Karkashdaladi Kwath is hypothesized to yield a superior efficacy because of its Strotovishodhana (channel cleansing), Aamapachana (digestion of metabolic toxins) properties.

Conclusion: This study may validate evidence-based Ayurvedic alternative to conventional treatment, supporting the integration of traditional formulations into mainstream management protocols.

Keyword: Dyslipidemia, Karkashdaladi Kwath, Medoroga, Medodushti, Navaka Guggulu.

I. INTRODUCTION

In Ayurveda, Medodushti is a pathological state where the metabolism of Medo Dhatu becomes severely compromised. In the Charaka Samhita, Medodushti is primarily described and elaborated under the clinical entity of Sthoulya and the pathology of Medovaha Srotodushti.^[1] The process is deeply tied to the concepts of Agni and Srotas. A sedentary lifestyle or excessive consumption of heavy, oily, and sweet foods weakens the specific tissuelevel fire responsible for fat metabolism (Medodhatvagni). Because this specific fire is weak, the nutrients meant to build healthy fat are processed incompletely, creating Ama (undigested metabolic toxins) and an abnormal, unripened form of fat. This low-quality fat builds up and causes Srotorodha (blockage of the body's microchannels).

This imbalance acts as the structural precursor to Medoroga (obesity and metabolic illness).^[2] Medodushti can be compared with Dyslipidemia. Dyslipidemia is characterized by elevated levels of total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), and triglycerides (TG), along with reduced levels of high-density lipoprotein cholesterol (HDL-C) in the plasma.^[3] It is a major risk factor for the initiation and progression of atherosclerosis and significantly contributes to the development of cardiovascular diseases (CVD) and stroke. Ayurveda's *Abaddha Medas* (unbound, circulating fat) corresponds directly to serum cholesterol and triglycerides. Medodushti manifests widely today through lifestyle-driven disorders. Globally, Metabolic Syndrome affects roughly 25% of the adult population. Studies evaluating lipid abnormalities report that Dyslipidemia is prevalent in 25–30% of urban populations and 15–20% of rural areas in industrializing regions.

This distribution reflects the direct impact of ultra-processed food and physical inactivity.^[4] Modern statins are the medicine of choice for Dyslipidemia, but they come with a long list of side effects, including headache, nausea, vomiting, gastrointestinal problems, disturbed sleep, muscle aches, myopathy. Therefore, seeking safe and efficient ayurveda treatment is necessary for a better solution. Most of contents of *Karkashdaladi Kwatha* are *Ruksha*, *Laghu*, *Sukshma*, *Katu Rasa*, *Katu Vipaka*, *Ushna Virya*. Drugs having *Rooksha*, *Teekshna*, *Ushna*, *Deepan*, *Pachan*,

Lekhan and *Chedan* properties are useful to produce *Strotovishodhana* and *Aamapachana* &

Lekhan of *Meda*. In *Navaka Guggulu*, maximum ingredients have *Rasa- Katu*, *Guna-*

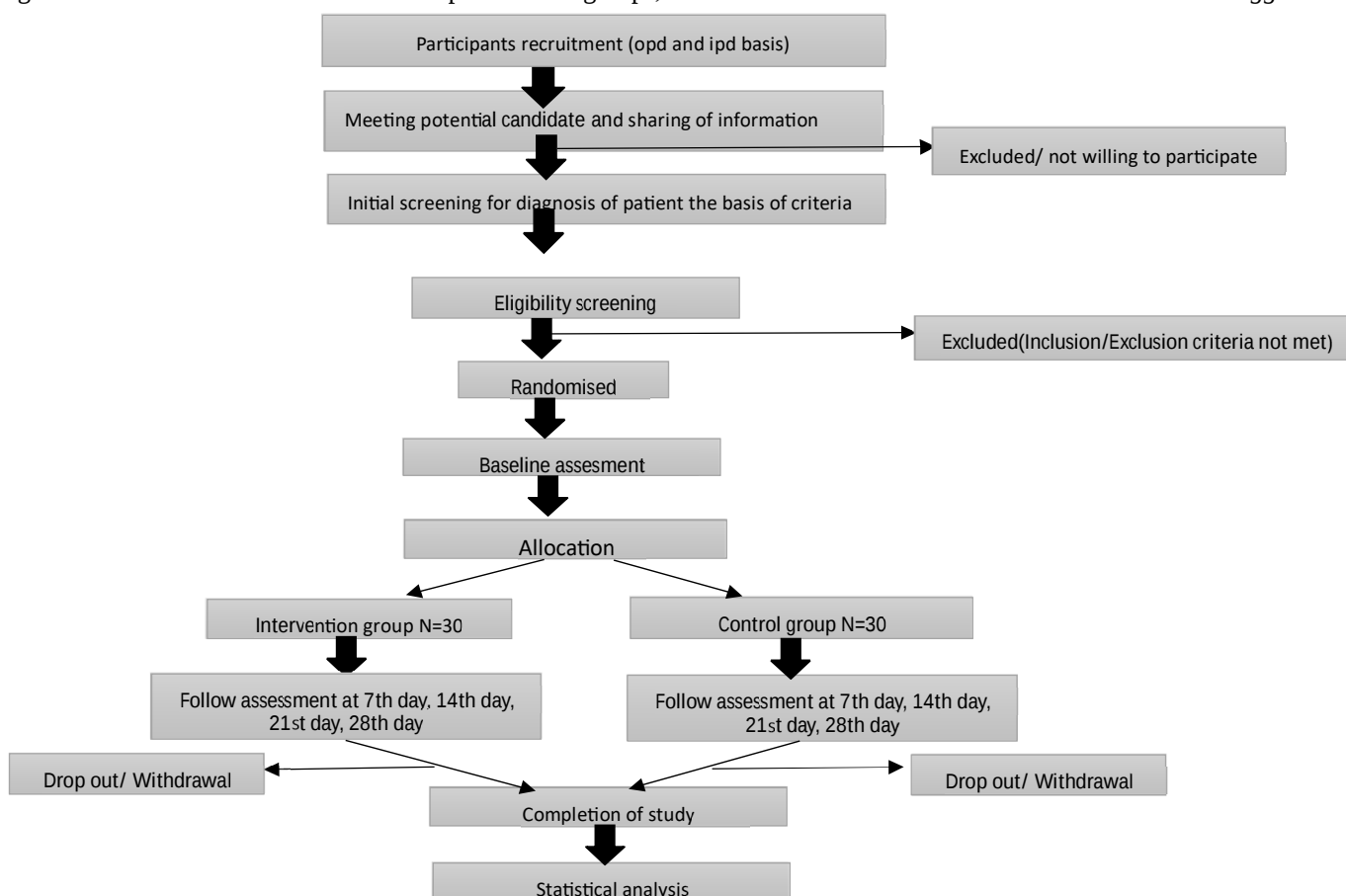
Laghu, *Ruksha*, *Virya- Ushna*, *Vipaka-Katu*, and so, it is very effective in *Agnivardhan* and *Amapachan* & *Lekhan* of *Meda*.

Numerous researches have been done on *Medoroga* but comparative evaluation of efficacy of *Karkashdaladi Kwath* and *Navaka Guggulu* has not been studied. So, there is a need to study the efficacy of *Karakashchadadi Kwath* in comparison to *Navaka Guggulu* to fill the research gap.

II. MATERIAL AND METHODS

A. Study Design

This study is single-centered, open-labelled, parallel comparative clinical trial. Study will be randomized using a computer generated allocation series. Patient will split into two groups, one for *Karkashdaladi Kwath* and other for *Navaka Guggulu*.



B. Participants

Patients will be recruited for the study from OPD and IPD of Institute for Ayurved Studies and Research, Faculty of Ayurved, Kurukshetra, Haryana.

☐ Sample Size and Randomization: 60 patients (30 per group), using a computer generated randomization schedule.

C. Eligibility

a) Inclusion Criteria ☐ Patients willing to sign the consent form.

- Patients between the age group of 25-45 years of either gender.
- Patients having underweight, normal weight, overweight, and class I obesity according to BMI.

BMI	Classification
<18.5	Underweight
18.5-24.9	Normal weight
25-29.5	Over weight
30-34.9	Class I obesity

- Diagnosed & confirmed cases of *Medodushti* (Dyslipidemia) & *Medoroga* on the basis of criteria given by NCEP-ATPIII.
[5] (Borderline High category).

Blood test	Desirable	Borderline High	High
Total Cholesterol	< 200 mg/dl	200 - 239 mg/dl	>240 mg/dl
Serum Triglycerides	< 150 mg/dl	150 -199 mg/dl	200-499 mg/dl (high)
LDL	< 100 mg/dl (optimal) 100 -129 (near optimal)	130- 159 mg/dl	160 -189 mg/dl (high)

b) Exclusion Criteria ☐ Patient not fulfilling inclusion criteria.

- Patient not willing for clinical trial.
- Patient below 25yrs of age group and above 45yrs of age group.
- Patients having medical history of – CAD, CKD, AKD, Uncontrolled Diabetes Mellitus, Uncontrolled Hypertension. ☐ Patient on steroid therapy and oral contraceptive therapy.
- Pregnant women and lactating mothers.

c) Criteria for Withdrawal

- ☐ Patient himself wants to withdraw from the clinical trial.
- ☐ During the course of trial if any serious condition or any serious adverse effect occurs this requires treatment withdrawal.

D. Ethical Considerations and Trial Registration

The Institutional Ethical Committee granted Ethical approval before the commencement of the study (SKAU/Acad/2024/10509).

The clinical Trial was registered with the clinical Trial Registry of India under registration number (CTRI/2024/07/070151).

E. Study Plan

Written informed consent will be taken from all participants about the study purpose and interventions in their preferred language. The patients will be asked about their medical history and physical examination will be conducted. Clinical finding will be assessed before during and after treatment by using assessment scale. Blood sample will be collected for lab investigations. Eligible patients who met all the inclusion criteria and did not meet any of the exclusion criteria will be enrolled into the study. Patients will be split into two group.

Group-A will receive *Karkashdaladi kwath* 50ml BD and Group-B will receive *Navaka Guggulu* 500mg BD for 28 days. After screening and enrollment of patients into the study at Day-0 (visit-1) weekly in treatment visits will be planned at Day-7 (visit-2), Day-14 (visit-3), Day-21(visit-4), Day-28 (visit-5) and post treatment follow up on Day-42 (visit6), Day-56 (visit-7). In every visit vital signs, physical examination will be assessed. Patients will be free to withdraw their consent from the study at any time without stating any reason.

F. Interventions

Group A *Karkashdaladi Kwath*^[6]

Table no: 1- contents of *Karkashdaladi Kwath*

S.n o	Drug	Botanical name	Part used	Rasa	Guna	Virya	Vipaka
1	<i>Patola</i>	<i>Trichosanthes dioica</i>	Leaf	<i>Tikata</i>	<i>Laghu, Ruksha</i>	<i>Ushna</i>	<i>Katu</i>
2	<i>Chitraka</i>	<i>Plumbago zeylanica</i>	Root bark	<i>Katu</i>	<i>Laghu, Ruksha, Tikshna</i>	<i>Ushna</i>	<i>Katu</i>
3	<i>Shatpushpa</i>	<i>Anethum sowa</i>	Seed	<i>Katu Tikta</i>	<i>Laghu, Ruksha, Tikshna</i>	<i>Ushna</i>	<i>Katu</i>
4	<i>Hingu</i>	<i>Ferula narthex</i>	Resin	<i>Katu</i>	<i>Laghu, Snigdha, Tikshna</i>	<i>Ushna</i>	<i>Katu</i>

Group B- *Navaka Guggulu*^[7]

Table no: 2- contents of *Navaka Guggulu*

s.no	Drug	Botanical Name	Part used	Rasa	Vipaka	Virya	Quantity
1.	<i>Sunthi</i>	<i>Zingiber Officinale</i>	Rhizome	<i>Katu</i>	<i>Madhura</i>	<i>Ushna</i>	1 part
2.	<i>Marich</i>	<i>Piper Nigrum</i>	Root	<i>Katu</i>	<i>Katu</i>	<i>Ushna</i>	1 part
3.	<i>Pippali</i>	<i>Piper Longum</i>	Root	<i>Katu</i>	<i>Madhura</i>	<i>Anushnashita</i>	1 part
4.	<i>Chitarak</i>	<i>Plumbago Zeylanica</i>	Root bark	<i>Katu</i>	<i>Katu</i>	<i>Ushna</i>	1 part
5.	<i>Haritaki</i>	<i>Terminalia Chebula</i>	Fruit	<i>Kashaya pradhan</i>	<i>Madhura</i>	<i>Ushna</i>	1 part
6.	<i>Amalaki</i>	<i>Emblica Officinale</i>	Fruit	<i>Amlarasa</i>	<i>Madhura</i>	<i>Shita</i>	1 part
7.	<i>Musta</i>	<i>Cyperus Rotundus</i>	Rhizome	<i>Tikta, Katu, Kashaya</i>	<i>Katu</i>	<i>Shita</i>	1part
8.	<i>Vidanga</i>	<i>Embelia ribes</i>	Fruit	<i>Katu, Kashaya</i>	<i>Katu</i>	<i>Ushna</i>	1 part
9.	<i>Vibhitaki</i>	<i>Terminalia Bellirica</i>	Fruit	<i>Kashaya pradhana</i>	<i>Madhura</i>	<i>Ushna</i>	1 part
10.	<i>Guggulu</i>	<i>Commiphora Mukul</i>	<i>Niryas</i>	<i>Tikta, Katu</i>	<i>Katu</i>	<i>Ushna</i>	9 parts

G. Assessment Criteria

1) Subjective Criteria

The following clinical findings will be assessed before, during and after treatment. According to WHO Assessment Scale of Clinical Features on the basis of classical ayurvedic text:

Scoring pattern for Subjective parameters

Kshudra Shwasa (Exertional Dyspnoea)

No Dyspnoea even after heavy work	0
Dyspnoea after moderate work but relieved later and tolerable	1
Dyspnoea after little work but relieved later and tolerable	2
Dyspnoea after little work but relieved later and not tolerable	3
Dyspnoea in resting condition	4

Trishna (Increased thirst)

Feeling of thirst (7 – 9 times/24 hours) & relieved by drinking water	0
Feeling of moderate thirst (>9 - 11 times/24 hours) & relieved by drinking water	1
Feeling of excess thirst (>11 – 13 times/24 hours) not relieved by drinking water	2
Feeling of sever thirst (>13 times) not relieved by drinking water	3

Moha (Drowsiness)

No drowsy (doing work satisfactorily)	0
Doing work with desire with initiation but late in time	1
Does work without desire with lot of mental pressure and late in time	2
Does not initiate work, does little work very slowly	3
Doesn't take initiative to work neither want to work even after pressure	4

Atinidra (Increased Sleep)

Normal & sound sleep for 6 – 8 hrs. /24 hrs. With feeling of lightness and relaxation in the body & mind	0
Sleep >8 -9 hrs. /24 hrs. with slight heaviness in the body	1
Sleep >9 - 10 hrs. /24 hrs. With heaviness in the body associated with <i>jrimbha</i>	2
Sleep >10 hrs. /24 hrs. with heaviness in the body associated with <i>jrimbha</i> & <i>tandra</i>	3

Krathana (Snoring)

No snoring	0
Occasional snoring	1
Snoring in some part of sleep	2
Snoring all the time of sleep	3
Interrupted sleep due to snoring and snoring accompanied by apnea	4

Angasada (Fatigue)

No heaviness	0
Occasionally feeling of heaviness for sometimes in hands and feet	1
Feeling of heaviness for sometimes in hands and feet not affecting activities of daily living	2
Daily feeling of heaviness over body, which leads to <i>Akarmanyata</i>	3
Most part of the body for long duration	4
All body for most part of the day	5

Atikshudha (Increased Appetite): (1 meal = about 350gm diet)

As usual / routine	0
Slightly increased (1 meal extra with routine diet)	1
Moderately increased (2 meals extra with routine diet)	2
Markedly increased (3 meals extra with routine diet)	3

Swedadhikya (Perspiration)

Sweating after heavy work	0
Profuse sweating after moderate work and movement	1
Sweating after little work and movement (stepping ladder etc.)	2
Profuse sweating after little work and movement	3
Sweating even at rest or in cold weather	4

Daurgandhya (Bad odour)

No odour	0
Bad odour but not offensive	1
Strong odour but can be lessened by use of deodorants or perfumes	2
Very strong odour even after using fragrances (use of deodorants or perfumes)	3

Alpapraan (General Debility)

Feeling of well being	0
Tired after doing strenuous physical activity	1
Tired after doing moderate physical activity but can perform daily Activity	2
Perform daily activity with difficulty	3
Extremely tired to carry out daily routine activity	4

Alpamaithuna (Loss of Libido)

Normal performance without external stimulation	0
Decreased frequency with normal performance	1
Decrease frequency with insufficiency	2
Normal performance with external stimulation	3
No sexual stimulation at all	4

2) Objective Criteria

Reduction in body weight

0%	Grade 0
1%-24%	Grade 1
25%-49%	Grade 2
50%-74%	Grade 3
75%-99%	Grade 4
100%	Grade 5

Reduction in BMI

0%	Grade 0
1%-24%	Grade 1
25%-49%	Grade 2
50%-74%	Grade 3
75%-99%	Grade 4
100%	Grade 5

Reduction in Serum cholesterol

0%	Grade 0
1%-24%	Grade 1
25%-49%	Grade 2
50%-74%	Grade 3
75%-99%	Grade 4
100%	Grade 5

Reduction in Serum triglyceride

0%	Grade 0
1%-24%	Grade 1
25%-49%	Grade 2
50%-74%	Grade 3
75%-99%	Grade 4
100%	Grade 5

Reduction in LDL

0%	Grade 0
1%-24%	Grade 1
25%-49%	Grade 2
50%-74%	Grade 3
75%-99%	Grade 4
100%	Grade 5

3) Laboratory Investigations

S no.	Parameters	Before Treatment	During Treatment					Post Treatment Follow up	
		0 th day	7 th day	14th day	21st day	28th day	42 nd day	56 th day	
1	Hb	√							
2	TLC	√							
3	DLC	√							
4	Blood sugar	√							
5	Serum Cholesterol	√				√		√	
6	Serum Triglyceride	√				√		√	
7	LDL	√				√		√	
8	SGOT	√							
9	SGPT	√							
10	Blood urea	√							
11	Serum creatinine	√							
12	Alkaline phosphatase	√							

III. OUTCOME MEASURES

- 1) Subjective: Clinical symptom scoring (Dyspnoea, thirst etc.) using standard Ayurvedic scales.
- 2) Objective: Laboratory tests including serum Cholesterol, Triglyceride, LDL.

IV. ANALYSIS

Data will be summarized as mean $\pm$ SD. Intergroup comparisons will utilize independent t-tests (or nonparametric equivalents), and within-group changes will be analyzed by paired t-tests.

Statistical significance will be set at $p < 0.05$ using standard statistical software.

V. DISCUSSION

Abnormal accumulation and vitiation of *Meda Dhatu*, known as *Medodushti*, give rise to various pathological conditions collectively referred to as *Medovikaras* or *Medoroga*. The pathogenesis begins with the derangement of *Agni*, resulting in the formation of *Ama Rasa*. This subsequently causes *Medodhatvagnimandya* (impairment of the metabolic activity of *Meda Dhatu*), leading to the improper and excessive production of *Meda Dhatu*. This pathological state is described as *Medodushti*. Dyslipidemia, a disorder characterized by abnormalities in lipid and lipoprotein metabolism, may manifest as either elevated or reduced levels of lipoproteins in the body.^[8] From an Ayurvedic perspective, Dyslipidemia can be correlated with *Medodushti*, which is considered the precursor stage of *Medoroga*. This protocol addresses a critical gap in Ayurvedic research by comparing a novel formulation, *Karkashdaladi Kwath*, with *Navaka Guggulu* in the management of *Medodushti*. In *Karkashdaladi Kwath*, *Rasa (Tikt, Katu)* initiates the scraping and reduction of *Kaph* and *Meda Dhatu*. *Guna (Laghu, Rooksha, Teekshan)* supports the breakdown, drying, and removal of excess *Meda*. *Veerya (Ushna)* boosts *Jathragni* and *Dhatvagni* (metabolic fire) to burn, metabolize Lipids and *Meda*. *Vipaka (Katu)* ensures the long-term reduction of fat and prevents its re-accumulation. In *Navaka Guggulu* Herbs like *Trikatu* and *Chitraka* possess *Katu Rasa* and *Ushna Virya*. They immediately stimulate *Agni*, forcing the body to digest *Ama*. *Shuddha Guggulu* is clinically celebrated for its *Lekhana* attribute. It binds to the *Kapha* and *Meda* (and physically scrapes it away from the cellular channels. In *Medodushti* as there is *Srotodhoosti* caused due to excessive or

aggravated *Meda*, *vidanga* and *Maricha* possess *Tikshna Guna*. They penetrate deeply into the micro-channels, liquefying the stagnant fat and flushing out the blockages, ultimately *Samprapti Vighatana*. By integrating classical Ayurvedic principles with modern clinical evaluation techniques, this study strives to validate the potential benefits, safety, and cost effectiveness of *Karkashdaladi Kwath* and *Navaka Guggulu* as an alternative treatment for *Medodushti*. The open label design is balanced by rigorous, objective outcome assessments which are expected to yield reproducible and clinically relevant data that could inform future large scale trials.

VI. CONCLUSION

This study protocol details an open labelled, parallel comparative clinical trial aimed at evaluating the efficacy and safety of *Karkashdaladi Kwath* and *Navaka Guggulu* in patients with *Medodushti* with special reference to Dyslipidemia. Successful results could pave the way for evidence based integration of Ayurvedic treatment modalities into modern healthcare practice.

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