

## RESEARCH PROTOCOL

# Protocol for an open-label randomized controlled exploratory trial of Homoeopathy on Dyslipidemia

Central Council for Research in Homoeopathy

### ABSTRACT

**Background and Objectives:** Dyslipidemia refers to the derangements of one or many of the lipoproteins; elevations of total cholesterol (TC), low-density lipoprotein (LDL) cholesterol and/or triglycerides (TGL), or low levels of high-density lipoprotein (HDL) cholesterol while elevation of lipoproteins alone is labeled as “hyperlipidemia.” It is a lifestyle disorder of concern today. Statins, fibrates, or a combination of statins with fibrates or niacin have been suggested for their beneficial role in lowering LDL-cholesterol levels, TGL, and increasing HDL-cholesterol levels, but with their adverse effects. Based on the positive results of few studies in the past, this protocol is designed to evaluate the effect of individualized homoeopathic medicines along with therapeutic lifestyle changes (TLC) on serum LDL-cholesterol levels.

**Materials and Methods:** The study will be a multicentric, open-label, randomized, placebo-controlled exploratory trial. Patients shall be randomized to Homoeopathy or placebo group of intervention using computerized randomization chart. The period of treatment cum follow-up shall be for 6 months. TLC shall be given to both the groups. Primary outcome measure will be to evaluate the changes in LDL-cholesterol levels at 3<sup>rd</sup> and 6<sup>th</sup> month from baseline.

**Discussion:** The study shall help in generating evidence about the role of homoeopathic intervention in dyslipidemia and also help in bringing about behavioral change in people about the adoption of a healthy lifestyle.

**Keywords:** Dyslipidemia, Exploratory trial, Individualized Homoeopathy, Therapeutic lifestyle changes

### INTRODUCTION

Dyslipidemia refers to the derangements of one or many of the lipoproteins; elevations of total cholesterol (TC), low-density lipoprotein (LDL) cholesterol and/or triglycerides (TGL), or low levels of high-density lipoprotein (HDL) cholesterol while the elevation of lipoproteins alone is labeled as “hyperlipidemia.” The term “atherogenic

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dyslipidemia” denotes a combination of elevated TGL and small-dense LDL particles and low levels of HDL-cholesterol. Dyslipidemia may result from over-production or lack of clearance of the lipoprotein particles or may be related to other defects in the apolipoprotein or metabolic enzyme deficiencies. The pathways and means of lipid metabolism in the human body reflect interactions of genetics, complex biochemical processes influenced by medical disorders, medications, and/or environmental factors.<sup>[1]</sup>

The role of high serum cholesterol, especially a high level of LDL-cholesterol, as a risk factor for coronary artery diseases is well-established.<sup>[2]</sup> Asian Indians have double the risk of coronary artery diseases than the whites; due to dyslipidemia that is characterized by borderline high TGL, elevated apolipoprotein-B, and reduced HDL in them. It is opined that although the TC levels in Asian Indians is similar or lower as compared to Caucasians, dyslipidemia is more common, which contributes to coronary heart disease (CHD).

The National Cholesterol Education Program (NCEP) expert panel on detection, evaluation, and treatment of high blood cholesterol in adults (Adult Treatment Panel III) reinforces LDL as the primary target of cholesterol-lowering therapy with the optimal goal of its level below 100 mg/dL. The panel recommends treatment beyond LDL lowering for patients with triglyceride levels of 200 mg/dL and above. Non-HDL-cholesterol, representing the sum of all atherogenic lipoproteins, has been identified as a secondary target of therapy in patients with elevated triglyceride levels. Managing and monitoring non-HDL-cholesterol level is found particularly important for Asian Indians. Lifestyle changes such as maintenance in regular aerobic physical activity, increase intake of Omega -3 polyunsaturated fatty acids in diet, and therapeutic interventions such as statins (HMG-CoA reductase inhibitors), fibrates, or a combination of statins with fibrates or niacin have been suggested for their beneficial role in lowering LDL-cholesterol levels, TGL, and increasing HDL-cholesterol levels, but with their adverse effects.<sup>[3]</sup>

An observational study conducted by Govekar *et al.*<sup>[4]</sup> on hyperlipoproteinemia during April 1992 - March 2003 on 322 patients showed improvement in 290 patients with a reduction in TC and TGL levels in 100 and 37 patients,

respectively. Though the study had been carried out on a large number of patients and throws light on the role of indicated homoeopathic medicines on patients with lipoproteinemia, it lacks statistical rigor and power. Another cohort study<sup>[5]</sup> with 57 patients of hypercholesterolemia treated with complex Homoeopathy showed a significant reduction in lipid parameters. A preclinical study on chickens<sup>[6]</sup> showed reduction in lipid parameters with homoeopathic medicine *Baryta carbonicum* and *Baryta muriaticum*. Another study<sup>[7]</sup> highlighted the remedial effect of homoeopathic drug *S. jambolanum* on carbohydrate and lipid metabolic disorders in streptozotocin induced diabetic rats. The lipid lowering effect of *Cholesterinum* has also been found.<sup>[8,9]</sup>

Keeping in view the current scenario of increasing risk of dyslipidemia leading to CHD in Indian population and dearth of conclusive evidence suggesting a beneficial role of Homoeopathy, there is a need to undertake a study for exploring the effectiveness of homoeopathic medicines in dyslipidemia along with TLC.

## STUDY OBJECTIVES

### Primary Objective

To evaluate the effects of individualized homoeopathic medicines along with TLC on serum LDL cholesterol levels.

### Secondary Objective

To evaluate the effects of individualized Homoeopathy + TLC on other serum lipid parameters:

- TC
- TGL
- HDL

## MATERIALS AND METHODS

### Settings

The study shall be conducted at seven centers of Central Council for Research in Homoeopathy: Regional Research Institute (H), Gudivada; Central Research Institute (H), Noida, Central Research Institute (H), Kottayam; Drug Standardisation Unit (H), Hyderabad; Clinical Research Unit (H), Tirupati; Clinical Research Unit (H), Puducherry; and Clinical Research Unit (H), Chennai.

Homoeopathic treatment will be given by trained homoeopathic physicians. Dietician/endocrinologist consultants will advise patients about diet and therapeutic lifestyle changes.

The study protocol is in accordance with the latest revision of the Helsinki declaration<sup>[10]</sup> on human experimentation and good clinical practices of India.<sup>[11]</sup> Although medicines proposed to be used during the study are known homoeopathic pharmacopoeia preparations, yet necessary clearance of the Ethical Committee and Scientific Advisory Committee has been obtained before undertaking the study. The trial is registered with the clinical trial registry of India (CTRI/2014/12/005257).

### Study Design

The study will be a multicentric, open-label, randomized, placebo-controlled exploratory trial. This design shall help in generating a treatment strategy indicated which will further give impetus for carrying out a double blind trial.

This study shall have two groups:

- Group 1: Individualized homoeopathic treatment + TLC.
- Group 2: Placebo Control + TLC.

### Selection of Patients

Patients shall be screened as per the criteria given in Table 1.

### Randomization and Allocation

The patients shall be assigned to one of the intervention groups with the aid of computer generated random numbers, using block randomization, generated at headquarters by the coordinator along with the biostatistician.

### Intervention

Each patient will be assessed after a detailed case taking as per the case recording format (CRF) and shall be given homoeopathic treatment as per the guidelines laid down by Hahnemann in the 5<sup>th</sup> edition of Organon of Medicine if he is allocated to Group I. In group II i.e., placebo, unimpregnated globules shall be dispensed to patients.

Selection of medicine will be made depending on the totality of symptoms. Use of appropriate repertory shall be done wherever required. Selection of potency and repetition of medicine will be as per discretion of investigator and as per patient's condition.

**Table 1: Eligibility criteria**

Inclusion criteria	Exclusion criteria
30-60 years of age	Patients with family history of hypertriglyceridemia
Patients having serum LDL-cholesterol levels >160 mg/dL	Patients with history of any cardiac event
Patients willing to participate in the study	Patients with any known systemic illness (cancer, hepatic diseases, renal diseases, diabetes, HIV, any abnormality in LFT, and KFT)
Controlled hypertensive patients who are on antihypertensive treatment and who fulfill above-mentioned 1 <sup>st</sup> , 2 <sup>nd</sup> , and 3 <sup>rd</sup> criteria	Patients on corticosteroids and hormonal treatment
Prediabetic patients with fasting blood sugar >110 and <126 mg/dL and who fulfill above-mentioned 1 <sup>st</sup> , 2 <sup>nd</sup> , and 3 <sup>rd</sup> criteria	Patients with excessive alcohol intake, (60 mL in case of males and 30 mL in case of females) for last 1 year
	Patients unable or unwilling to give informed consent
	Pregnant and lactating mothers

LDL: Low-density lipoprotein; LFT: Liver function test; KFT: Kidney Function test

### Concomitant Therapy

TLC includes physical activity and diet modification which shall be given to all the patients after eliciting baseline diet, physical activity information in consultation with the dietician/endocrinologist.

### Treatment Regimen/Repetition Schedule

Individual homoeopathic medicines will be administered orally. The medicine will be repeated depending on the potency and complaints of the patient in accordance with the principles of Homoeopathy. Once the improvement sets in placebo will be continued until the medicine continues to act.

### Follow-up

The enrollment period will be for 6 months, and each enrolled patient shall be followed every month for a period of 6 months. Required investigations of each patient shall be conducted at baseline 3<sup>rd</sup> and 6<sup>th</sup> month [Table 2]. Physical activity of patient will be assessed by physical activity scoring system<sup>[12]</sup> every month as a part of TLC. Dietician/endocrinologist will advise patients about diet and therapeutic lifestyle changes during the study and adherence will be assessed by diet adherence score<sup>[12]</sup> at every month.

### Early Withdrawal of Patients

Patients developing any cardiac event, frank diabetes, any systemic illness (cancer, hepatic diseases, renal diseases, diabetes, HIV, any abnormality in liver function test, and kidney function test, unwilling to participate further, or with any other issue as per the discretion of investigator shall be withdrawn from the study.

**Table 2: Time line and schedule of enrollment, intervention, and assessment**

Time point	Study period								Close-out
	Enrollment	Allocation	Post allocation in month						
	-1	0	1	2	3	4	5	6	
Enrollment	X								
Eligibility screen	X								
Informed consent	X								
Allocation		X							
Interventions									
Homoeopathy + TLC			X	X	X	X	X	X	
Placebo + TLC			X	X	X	X	X	X	
Assessments									
Age	X								
Weight	X				X			X	
Height	X								
Waist circumference	X				X			X	
Hip circumference	X				X			X	
Blood pressure (systolic/diastolic)	X		X	X	X	X	X	X	X
LDL-cholesterol	X				X			X	X
TC	X				X			X	X
HDL	X				X			X	X
Triglycerides	X				X			X	X
VLDL	X				X			X	X
Apolipoprotein-A	X				X			X	X
Apolipoprotein-B	X				X			X	X
Non-HDL-cholesterol	X				X			X	X
TC-HDL	X				X			X	X
Apolipoprotein ratio	X				X			X	X
Apolipoprotein-A: apolipoprotein-B	X				X			X	X
Fasting blood glucose	X		X	X	X	X	X	X	X
TSH	X								
Liver function test	X				X			X	X
Kidney function test	X				X			X	X
Complete haemogram	X								
Physical activity score	X		X	X	X	X	X	X	X
ECG	X				X			X	
Physical activity adherence	X		X	X	X	X	X	X	X
Diet adherence	X		X	X	X	X	X	X	X

TLC: Therapeutic lifestyle changes; TSH: Thyroid stimulating hormone; LDL: Low-density lipoprotein; HDL: High-density lipoprotein; VLDL: Very low-density lipoprotein; TC: Total cholesterol; ECG: Electrocardiogram

### Patient Compliance Monitoring

All the patients shall be motivated to adhere to study treatment and for measurement of various investigations from time to time by the investigator. To check the compliance a telephonic recall about adherence to diet and exercise shall be given to the patient every week.

### Study Monitoring

The study will be monitored on regular basis. Monthly assessments of case records at headquarters as well as on-site visits from time to time will be carried out.

### STUDY OUTCOMES

#### Primary Study Endpoint (Primary Outcome Measure)

- To evaluate the changes in LDL-cholesterol levels at 3<sup>rd</sup> and 6<sup>th</sup> month from baseline.

#### Secondary Study Endpoints (Secondary Outcome Measures)

To evaluate the changes in:

- TC at 3<sup>rd</sup> and 6<sup>th</sup> month from baseline
- TGL at 3<sup>rd</sup> and 6<sup>th</sup> month from baseline
- HDL at 3<sup>rd</sup> and 6<sup>th</sup> month from baseline.

## DATA COLLECTION

Standard CRF and predesigned spread sheet shall be used for data capturing. Data recording shall be done through validated scoring systems and results of timely investigations.

### Sample Size Determination

Being an exploratory study, there is no definite calculation of sample size; however, in this study, 100 patients (50 in each group) shall be enrolled. With dropout rate of 20%, the total sample size shall be 120 (60 in each group).

### Statistical Methods/Statistical Evaluation

The principal analyses of primary and secondary outcomes will employ the “intent-to-treat” approach. All the data shall be assessed for normal distribution. All statistical tests will be done as follows: Non-parametric tests for categorical data, ordinal data, and parametric test for continuous data.

## DISCUSSION

Lifestyle disorders are diseases of civilization. As can be understood, they are caused by an inappropriate relationship of people with their environment and their own genetic/familial/inherited tendencies to suffer from a diseased condition. Hyperlipidemia/dyslipidemia, mostly an asymptomatic disease, is a progressing lifestyle disorder today and needs to be managed with timely medical treatment and lifestyle modification before it leads to its complications.

Very few clinical,<sup>[4,5]</sup> preclinical studies<sup>[6-8]</sup> and case reports<sup>[9,13,14]</sup> in the past with their own strengths and weaknesses reflect the positive directions of using homoeopathic medicines in hyperlipidemia, however no systemic reviews and controlled clinical trials have been carried out till date to explore and reckon its effectiveness/efficacy.

This study protocol is designed as a randomized controlled trial with comparator arm as placebo along with TLC in both the groups and shall help in generating evidence about the role of homoeopathic intervention in hyperlipidemia. Medicines prescribed as per homoeopathic principles covering the entire symptomatology and individual aspects of each patient shall be helpful in improving the overall health and well-being of the patient. Further, the response of the effects of the remedies prescribed shall be

helpful in developing an effective treatment strategy. It is also expected that the information on behavioral change for healthy life style (regular physical activity in the form of walk/yoga, consumption of healthy diet and avoidance of tobacco and alcohol etc.) given to the patients shall also inculcate a sense of self-care which is the need of the hour.

The protocol shall generate data that can be reported as per CONSORT guidelines for reporting randomized trials with parallel groups,<sup>[15]</sup> and the reporting data on a homoeopathic treatments (RedHot) supplement to CONSORT.<sup>[16]</sup> It is in accordance with the SPIRIT 2013.<sup>[17]</sup> Further, this study involves administration of individualized homoeopathic medicine with the involvement of homoeopathic experienced doctors in treating patients suffering from dyslipidemia, using validated assessments which will be amenable to the profession at large thus covering all the domains of model validity of homoeopathic trials.<sup>[18]</sup>

## TRIAL STATUS

The study is in the pretrial phase in which 1469 patients have been screened, and 156 patients have been enrolled till date.

## CONTRIBUTORS

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## Conflicts of Interest

There are no conflicts of interest.

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### डिसलिपिडिमिया में होम्योपैथी के खुले यादृच्छिक खोजपूर्ण नियंत्रित परीक्षण के लिये प्रोटोकॉल

#### पृष्ठभूमि और उद्देश्य:

एक या एक से अधिक लाइपोप्रोटीन के अनियंत्रित होने को डिसलिपिडिमिया कहा जाता है, जिसमें शामिल है सम्पूर्ण कोलेस्ट्रॉल के स्तर का बढ़ना, निम्न घनत्व वाले लाइपोप्रोटीन कोलेस्ट्रॉल और/या ट्राइग्लिसराइड या उच्च घनत्व वाले लाइपोप्रोटीन का स्तर कम होना जबकि लाइपोप्रोटीन अकेले का बढ़ना 'हाइपरलिपिडिमिया' अंकित किया गया है। आज यह ध्यान देने योग्य प्रमुख जीवनशैली रोग है। निम्न घनत्व वाले कोलेस्ट्रॉल व ट्राइग्लिसराइड के स्तर को कम करने और उच्च घनत्व वाले कोलेस्ट्रॉल को बढ़ाने के लिए स्टेटिन, फाइब्रेट्स या दोनों का सम्मिश्रण अथवा नाइसिन लेने का सुझाव, उनकी लाभकारी भूमिका की वजह से दिया जाता है किन्तु इनके कुछ दुष्परिणाम भी हैं। पूर्व में कुछ अध्ययनों में पाये गए सकारात्मक परिणामों के आधार पर यह संलेख संरचित किया गया है ताकि उपचारात्मक जीवनशैली के साथ-साथ व्यक्तिशः होम्योपैथिक औषधियों के प्रभाव का मूल्यांकन स्तोद समाहित निम्न घनत्व वाले लाइपोप्रोटीन कोलेस्ट्रॉल स्तरों पर किया जा सके।

#### सामग्रियाँ और विधियाँ:

प्रस्तुत अध्ययन एक खुला नामपत्र यादृच्छिक नियंत्रित भेदक परीक्षण रहेगा। कम्प्यूटर आधारित यादृच्छिक चार्ट का उपयोग कर रोगियों को होम्योपैथी या प्लासिबो हस्तक्षेप समूह में यादृच्छिक किया जाएगा। चिकित्सा अवधि या पुनरागमन 6 माह के लिए होगा। उपचारात्मक जीवनशैली परिवर्तन दोनों समूहों को कराये जाएंगे। प्राथमिक परिणामों के मापन से निम्न घनत्व लाइपोप्रोटीन कोलेस्ट्रॉल के स्तर में तीसरे और छठवें माह में परिवर्तन का मूल्यांकन आधार रेखा से किया जाएगा।

#### चर्चा:

प्रस्तुत अध्ययन हाइपरलिपिडिमिया के प्रकरणों में होम्योपैथिक चिकित्सा की भूमिका और हस्तक्षेप के लिए सबूत पैदा करने में मदद करेगा और साथ ही स्वस्थ जीवनशैली को अंगीकार करने के प्रति लोगों के व्यवहार में परिवर्तन लाने में मदद करेगा।

## **Protocolo para ensayo exploratorio, controlado, aleatorizado y de diseño abierto de la Homeopatía en la dislipidemia**

### **RESUMEN**

**Fundamento y objetivos:** La dislipidemia se refiere a la alteración de una o más lipoproteínas, el aumento del colesterol total, las lipoproteínas de baja densidad (LDL) y/o los triglicéridos, o un nivel reducido de las lipoproteínas de alta densidad (HDL). El aumento exclusivo de las lipoproteínas se denomina "hiperlipidemia o hiperlipemia". Es un trastorno del estilo de vida de gran preocupación. Para el tratamiento se han propuesto las estatinas, los fibratos o una combinación de estatinas con fibratos o niacina, debido a su efecto beneficioso al reducir los niveles del colesterol LDL y los triglicéridos, a la par que aumentan los valores del colesterol HDL. Sin embargo, poseen efectos adversos. A partir de los resultados positivos de algunos estudios realizados en el pasado, se ha diseñado este protocolo para evaluar el efecto que los remedios homeopáticos individualizados junto con un cambio en el estilo de vida (CEV) tienen en los valores del colesterol LDL sérico.

**Materiales y métodos:** El estudio será un ensayo exploratorio aleatorizado, controlado con placebo, multicéntrico y de diseño abierto. Los pacientes serán aleatorizados a un grupo homeopático o a un grupo placebo utilizando un programa de aleatorización por ordenador. El periodo de tratamiento con el seguimiento tendrá una duración de 6 meses. Cambios de estilo de vida terapéuticos (CTE) se les dará a ambos grupos. El parámetro primario será la evaluación de los cambios en los valores del colesterol LDL a los 3 y 6 meses, en comparación con los valores iniciales.

**Discusión:** El estudio contribuirá a aportar evidencias sobre el papel del tratamiento homeopático en la dislipidemia, así como a encontrar y dar pautas conductuales a las personas para adoptar un estilo de vida sano.