**RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES,**

**BANGALORE KARNATAKA**

**ANNEXURE–II**

**PROFORMA FOR REGISTRATION OF SUBJECTS FOR**

**DISSERTATION**

| **1** | **Name of the candidate and address(in block letters)** | **:** | **Dr. RAVISHANKAR S**  **DEPARTMENT OF GENERAL MEDICINE**  **NAVODAYA MEDICAL COLLEGE**  **HOSPITAL AND RESEARCH CENTRE,**  **RAICHUR-584103.** |
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| **2** | **Name of the institution** | **:** | **NAVODAYA MEDICAL COLLEGE HOSPITAL & RESEARCH CENTRE,**  **RAICHUR-584103** |
| **3** | **Course of study and subjects** | **:** | **M.D. GENERAL MEDICINE** |
| **4** | **Date of admission to the course** | **:** | **12TH OCTOBER 2023** |
| **5** | **Title of Topic** | **:** | **“A PROSPECTIVE STUDY OF SERUM URIC ACID AND LIPID PROFILE IN HYPERTENSIVE PATIENTS.”** |

| **6** | **A brief resume of the intended work** | |
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|  | **6.1** | **Need for the study** |
|  |  | Hypertension is one of the most vital noncommunicable diseases contributing to the global burden of morbidity and mortality and one of the vital causes leading to death.1 Hypertension has been associated with an increased incidence of cardiovascular pathology, which includes coronary artery heart disease, heart failure, ischemic and hemorrhagic stroke, renal disease, and peripheral arterial disease. It has seemed to be linked with cardiovascular risk factors, and so the risk amount increases with the total weight of risk factors.2 Even though it is present worldwide, the major toll occurs in developing nations rather than developed nations due to unawareness and inadequate treatment. Proper educational strategies will help to manage the epidemics of hypertension.3  Even though the treatment of hypertension seems to reduce the risks of cardiovascular and renal pathology, the majority of the hypertensive group is not treated sufficiently, due to unawareness of the problem. Among hypertensive, renal disease is an important complication, especially with more severe Hypertension.4 The Asia Pacific cohort studies collaboration demonstrated the log-linear relationship of blood pressure with ischemic and hemorrhagic stroke, Ischemic heart disease, congestive cardiac failure, renal insufficiency, and obstructive sleep apnea, till cardiovascular death that continues down to at least 115/75 mmHg.5  Hypertension is one of the components of the metabolic syndrome and an increased level of triglycerides, cholesterol, LDL, and VLDL, with decreased levels of HDL, has been associated with hypertension. Metabolic syndrome comprises a group of parameters that predict the risk of occurrence of cardiovascular disease and diabetes mellitus.6  Hypertension is part of metabolic syndrome that has clearly been shown to increase the risk for cardiovascular morbidity, and mortality,  Uric acid is one of the by-products of the metabolism of purine produced in blood from endogenous purine (2/3) substances or from the diet (1/3). Uric acid is considered to be one of the independent risk factors for hypertension and its levels also tend to correlate with the severity of hypertension.7 Uric acid tends to have a pathogenic part in hypertension mediated by various actions such as inflammation, vascular smooth muscle cell proliferation in renal microcirculation, dysfunction of endothelium and the renin-angiotensin-aldosterone system activation  Dyslipidemia has been found associated with elevation of uric acid levels and raise in any one of the lipid parameters has been found to increase the uric acid level.8 Uric acid is not considered a criterion for the diagnosis of metabolic syndrome, but some studies have observed a correlation between high levels of uric acid and metabolic syndrome in different populations.9  Hence, this study to assess the levels in serum uric acid and lipid profile, and to determine the association of uric acid and lipid profile in hypertensive patients. |
|  | **6.2** | **Review of Literature** |
|  |  | A study was conducted by Wang Y et al(2023), on adults aged 20 years and older to investigate the association between serum uric acid levels and hypertension. Study results indicate that serum uric acid levels were positively correlated with the risk of hypertension. The study found an interaction between uric acid and hypertension and age, sex, race, education, and smoking, except for marital status and drinking status.10  A study was conducted by Bhosale A et al(2022), on 235 cases with hypertension to determine the prevalence and association of hyperuricemia with diagnosed cases of hypertension. The prevalence of hyperuricemia was seen as 27.7% among cases with hypertension. A significant correlation was observed between serum uric acid levels and systolic and diastolic blood pressure i.e. serum uric acid levels increases with increase in blood pressure. Study concluded that the prevalence of hyperuricemia was significantly higher in diagnosed subjects with hypertension, affecting every one out of four individual. Mean serum uric acid levels were significantly associated with increase in systolic and diastolic blood pressure.11  A study was conducted by Kumar R et al(2022), comprising 30 healthy individuals and 30 hypertensive individuals to analyze the possibility of correlation existing between fasting serum uric acid levels and fasting serum lipid parameters in hypertension. Dyslipidemia is seen in hypertensive individuals. Elevation of triglycerides, rise in total cholesterol, raised LDL, and raised VLDL are observed in hypertensive individuals. The study observed the levels of HDL were low in hypertensive individuals. Elevation of serum uric acid level is seen in hypertensive. Both dyslipidemia and hyperuricemia were observed to be elevated with an increase in age in hypertension.12  A study was conducted by Anil KM et al(2020), on 200 study participants to assess the lipid profile abnormalities among primary hypertensive patients attending tertiary care centers. The mean values of the total cholesterol, low-density lipoprotein (LDL) cholesterol, and triglycerides were significantly higher in hypertensive patients compared to a non hypertensive group. The mean high-density lipoprotein (HDL) cholesterol was lower among hypertensive patients than non hypertensive patients. Studies showed a combination of dyslipidemia and hypertension increases the risk of cardiovascular diseases, stroke, etc. Studies recommend that early detection of dyslipidemia in hypertensive patients and aggressive treatment of both conditions should be carried out to prevent complications.13  A study was conducted by Jagannadha PD et al(2018), on 90 subjects divided into two groups to determine the association of uric acid and lipid profile with hypertension of recent onset. A significant difference in uric acid levels between the test group and control group both among males and females was observed. Serum Uric acid, TC, HDL-C, LDL-C, and TG’S were determined by enzymatic methods using commercially available kits on a fully automated analyzer. VLDL was a calculated parameter. Among the lipid profile parameters, the mean Total cholesterol and Triglycerides were high in cases as compared to controls. A study found a significant association of uric acid with Hypertension    among males and females was observed in our study. Among the lipid profile parameters, a significant association was found between Total cholesterol, triglycerides, and hypertension.14  A study was conducted by Mashooq AD et al(2017), on one hundred hypertensive individuals to determine the frequency of dyslipidemia in patients with hypertension. All the individuals were assessed for dyslipidemia after at least 14 hours fasting. The frequency of dyslipidemia was male gender predominant along with the urban population. The study found hypercholesterolemia, hypertriglyceridemia, low HDL, and raised LDL and VLDL seen in patients with hypertension. Thus correlation between dyslipidemia and hypertension should be properly evaluated and treated to save the patients from long-term chronic complications associated with hypertension and hyperlipidemia.15  A study was conducted by Vishnu RS et al(2013), on a total of 300 patients of which 150 were cases and 150 controls to evaluate a relationship between the serum uric acid levels and severity & duration of hypertension. Study findings showed a direct relation between hyperuricemia and hypertension. The study showed that the serum uric acid levels were significantly increased in patients with Stage 2 hypertension in comparison with those with stage 1 hypertension showing that the severity of hypertension also related to the serum uric acid levels. The study also showed that the duration of hypertension had a significant impact on the serum uric acid levels, those with a longer duration of hypertension had significantly raised serum uric acid levels when compared with those of a lesser duration serum uric acid can be used as a prognostic factor in hypertension.16 |
|  | **6.3** | **Objectives of the study** |
|  |  | 1. To measure fasting serum uric acid levels in hypertensive individuals and non hypertensive individuals 2. To measure fasting serum levels of lipid parameters triglycerides, total cholesterol, LDL, VLDL, and HDL in hypertensive individuals and non hypertensive individuals 3. To analyze the possibility of correlation existing between fasting serum uric acid levels and fasting serum lipid parameters in hypertension |
| **7** | **Materials and methods** | |
|  | **7.1** | **Source of data** |
|  |  | All primary hypertensive cases and age and gender-matched controls attending outpatient department and admitted cases in Department of General Medicine at Navodaya Medical College Hospital and Research Centre, during 18 months considering the inclusion and exclusion criteria. |
|  | **7.2** | **Methods of collection of data(including sampling procedure, if any)** |
|  |  | 1. **Type of Study: C**ase control study 2. **Place of study**: Department of General Medicine, Navodaya Medical College Hospital and Research Centre, Raichur 3. **Duration of Study**: 18 months. 4. **Sample Size** : 150 patients ( 75 in each group)   **Sample size calculation:**  Prevalence of hyperuricemia was seen as 27.7% among cases with hypertension.11  Zα/2 = 1.96 standard normal variate at 95% confidence level.  e = 10% precision  The formula used for sample size calculation is,  n = (Zα/2)2 (p)(1-p)  e2  n = (1.96)2 (0.27)(0.73)  (0.1)2  n = 74.55 ~ 75 samples  Therefore, the minimum sample size is 75 in each in cases and controls.   1. **Inclusion criteria:** 2. Hypertensive individuals aged between 35-65 years with BP ≥140/90 (Cases - Group A). 3. Non hypertensive individuals aged between 35-65 years with BP < 140/90 (Controls - Group B). 4. **Exclusion criteria:** 5. Diabetes mellitus 6. Ischemic heart disease 7. Renal disease 8. Chronic liver disease 9. Familial hyperlipidemia 10. Patients on lipid-lowering drugs 11. Obese, and Gout. 12. Pregnancy     **Methodology:**   * Prior to data collection, the purpose and procedures of the study will be explained to eligible patients, and informed consent will be obtained. * The study will adhere to ethical principles, and clearance will be obtained from the institutional ethics committee. * The study include primary hypertensive cases and age and gender matched controls and they will be divided into two groups,   **Group A:** Hypertensive individuals (Cases)  **Group B:** Non hypertensive individuals ( Controls)   * Detail history will be taken and relevant clinical examination will be performed. * The routine and specific investigations (if necessary) will be advised while to evaluate the dyslipidemia the patients will be advised for at least 12 hours fasting and then blood sample will be drawn and sent to laboratory for biochemical analysis. Serum was separated by centrifugation and analyzed by the standard methods. * After clot formation the specimens will be centrifuged at 3000rpm for 10 min. * The obtained serum will be analysed for Uric acid, Total cholesterol, HDL, LDL, Triglycerides using commercial kits on a fully automated Mind ray BS 380 analyser. VLDL values will be obtained by calculation (friedwalds formula).   **Statistical analysis:**  Data will be entered into Microsoft excel data sheet and analyzed using SPSS software. Continuous variables will be presented as mean and standard deviation. Categorical variables are presented as frequencies and percentages. To evaluate the difference between the two groups in continuous variables, the normality test will be performed followed by the independent T-test. For categorical data, a chi-square test or Fisher’s exact test will be used. P value (probability that the result is true) of <0.05 will be considered as statistically significant. |
|  | **7.3** | **Does the study require any investigation or intervention to be conducted on patients other than humans or animals? if so please describe briefly** |
|  |  | **Yes, the** following investigations will be done,  **Laboratory investigations:**   * + Serum Triglyceride   + Serum Cholesterol   + Serum VLDL   + Serum HDL   + Serum LDL   + Serum Uric acid   + Blood glucose   + Serum urea   + Serum creatinine |
|  | **7.4** | **Has ethical clearance been obtained from your institution in case of 7.3?** |
|  |  |  |
| **8** | **List of references:**   1. Bhosale A, Khedkar S, Khade SK, Reddy MM. Study of serum uric acid levels in essential hypertension. International Journal of Health Sciences.2022;6(S7):3528–36. 2. Kumar R, Prabhu A. A prospective study of correlation between serum uric acid and dyslipidemia in essential hypertension. IAIM, 2019; 6(8): 70-77. 3. Anil KM, Surada C, Rajyalakshmi C. A study of lipid profile abnormalities among patients with essential hypertension attending tertiary care centre. International Journal of Contemporary Medical Research. 2020;7(1):A1-A4. 4. Jagannadha PD, Sujatha P, Sunanda V, Apparow DN, Kodal V. Study of uric acid and lipid profile in recent onset essential hypertension. International Journal of Clinical Biochemistry and Research, April-June, 2018;5(2):301-305. 5. A Mourad, S Carney, A Gillies, B Jones, R Nanra, P Trevillian. Arm position and blood pressure: a risk factor for hypertension? J Hum Hypertens., 2003; 17: 389-395. 6. AF Jones, GYH Lip. Lipoprotein (a): more than just a bystander in the pathophysiology of hypertension? J Hum Hypertens., 1998; 12: 75-77. 7. AH Maitland-van der Zee, OH Klingel, et al. TA Grynberg. Hypertension prevention: from nutrients to (fortified) foods to dietary patterns. Focus on fatty acids. J Hum Hypertens., 2005; 19: S25-S33. 8. Alderman Michael H, Cohen Hillel, Madhavan Shantha, Kivlighn Salah. Lipid metaboisum in hypertension. J metobolic syndrome, 2005; 9: 133-135. 9. B Wizner, B Gryglewska, J Gasowski, J Kocemba, T Grodzicki. Normal blood pressure values as perceived by normotensive and hypertensive subjects. J Hum Hypertens., 2003; 17: 87-91. 10. C Cuspidi, C Sala. Home blood pressure measurement: a means for improving blood pressure control? J Hum Hypertens., 2008; 22: 159-162. 11. CE Chiang, CH Chen. Hypertension in the Asia-pacific region. J Hum Hypertens., 2008; 22: 441-443. 12. Christoph Bickel, Hans J. Rupprecht, Stefan Blankenberg, et al. Serum Uric Acid as an Independent Predictor of Mortality in Patients With Angiographically proven Coronary Artery Disease. Am J Cardiology, 2002;89: 12-17 13. Wang Y, Ouyang Y, Zhang Y. Relationship between serum uric acid and hypertension in the general US population aged 20 years and older: A cross-sectional study based on NHANES 2007 to 2016. Medicine (Baltimore). 2023 Sep 22;102(38):e34915. 14. Mashooq AD, Syed FAH, Syed ZAS, Hamid NAM, Zulfiqar AQ, Imran K. Dyslipidemia in Patients with Essential Hypertension. Indo Am. J. P. Sci;2017;4(03):511-15. 15. Vishnu RS, LK Dash, Malati M. Observation of Serum Uric Acid Levels in Essential Hypertension. Kerala Medical Journal. 2013;6(3):65-7 | |

| **9.** | **Signature of the Candidate** | |  |
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| **10.** | **Remarks of the Guide** | |  |
| **11.** | **11.1** | **Name and Designation of Guide (In block letters)** | **Dr SIDDALINGA REDDY**  **PROFESSOR,**  **DEPARTMENT OF GENERAL MEDICINE,**  **NAVODAYA MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTRE, RAICHUR– 584103.** |
|  | **11.2** | **Signature** |  |
|  | **11.3** | **Co-guide(if any)** |  |
|  | **11.4** | **Signature** |  |
|  | **11.5** | **Head of the Department** | **Dr. SHANKARAPPA M. MUDGAL PROFESSOR & HOD,**  **DEPARTMENT OF GENERAL MEDICINE,**  **NAVODAYA MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTRE, RAICHUR– 584103.** |
|  | **11.6** | **Signature** |  |
| **12** | **12.1** | **Remarks of Chairman and Principal** |  |
|  | **12.2** | **Signature** |  |

**PATIENT CONSENT FORM**

**“A PROSPECTIVE STUDY OF SERUM URIC ACID AND LIPID PROFILE**

**IN HYPERTENSIVE PATIENTS.”**

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_​have been told in a language that I understand about the aims, objectives, methods, and the duration of study. The benefits, foreseeable risks, or discomfort resulting from participation have been explained by the investigator. I have been told that I/he/she/have/has the full right to claim for free treatment for research-related injury if any by the investigator and compensation for disability/death, resulting from such injury. I have been told that the study is a research procedure, that my/ his/ her participation is voluntary, and I/he/ she reserve the full right to withdraw from the study at my/ his / her own initiative at any time, without penalty or loss of benefits, or giving any reason and that right to participate or withdraw from the study at any stage will not prejudice my/ his/ her rights and welfare. I have also been assured that confidentiality will be maintained and only be shared for academic purposes.

I hereby give consent to participate in the aforesaid study. I am also aware that I can withdraw this consent at any later date if I wish to. This consent form is being signed voluntarily indicating my agreement to participate in the study, until I decide otherwise. I understand that I will receive a signed and dated copy of this form.

If I have any doubts/questions pertaining to the aforesaid study. I have been asked to contact – DR. RAVISHANKAR S

I have signed this consent form before my participation in this study.

Signature/thumb impression of the research subject:

Date:

Place:

Name of the witness:

Signature

Date:

Place:

**PROFORMA**

**“A PROSPECTIVE STUDY OF SERUM URIC ACID AND LIPID PROFILE**

**IN HYPERTENSIVE PATIENTS.”**

IP/OP No: Date:

Name of the patient:

Age: Sex:

Address:

Complaints:

**Past History:**

* Diabetes mellitus
* Hypertension
* Ischemic Heart disease
* Lung disease
* Thyroid disease
* Renal disease
* Liver disease
* Any other illness

**Drug History:**

* Diuretics
* Lipid lowering agents:
* Steroids
* Others

**Personal History:**

* Diet
* Smoking
* Alcohol

**Family History:**

* Cardiovascular disease
* Hypertension
* Hyperlipidemia:
* Other

**General physical examination:**

* Built
* Height
* Weight
* Nutrition
* Pallor
* Icterus
* Clubbing
* Oedema
* Cyanosis
* Lymphadenopathy

**Vitals:**

* BP (At 30 min interval) 1.\_\_\_\_\_\_\_ 2.\_\_\_\_\_\_\_\_ 3.\_\_\_\_\_\_\_
* Pulse
* Respiratory rate:

**Systemic examination:**

* Respiratory System
* Cardiovascular System
* Abdominal System
* Nervous System

**Investigations:**

* Serum Triglyceride mg/dl
* Serum Cholesterol mg/dl
* Serum VLDL mg/dl
* Serum HDL mg/dl
* Serum LDL mg/dl
* Serum Uric acid mg/dl
* Blood glucose mg/dl
* Serum urea mg/dl
* Serum creatinine mg/d