

Study Protocol

Title of Article: kidney function test for screening of the kidney disease among hypertensive patients.

Abstract:

Background: Kidney disease results in some loss of renal function and can lead to kidney failure, which is Renal failure is defined as the full loss of kidney function. Renal failure is the last stage of kidney disease, at which point dialysis or a kidney transplant are the only treatments available. The prevalence rate of kidney disease among hypertensive patients in India is 29.8%.

Objective: 1.To evaluate the kidney function test by using serum creatinine, blood urea nitrogen and uric acid among hypertensive patients.

2. To determine the prevalence of kidney disease among hypertensive patients

3. To associate the demographic variables with the selected kidney function test among hypertensive patients.

Methodology: It is a cross sectional, analytical hospital based study. The patients of hypertension has selected for the study. Patients are chosen based on inclusion criteria, and the nature and aim of the study are explained in detail and the written and informed consent, from the subject will be taken before data collection by the investigator after that the blood and urine samples will be taken from the hypertensive patients for further investigation respectively. The setting of the study is selected hospitals of Vidarbha Region. The Ethical approval obtained from Institution Ethical Committee, DMIMS (DMIMS (DU)/IEC/2020-21/283).

Expected Results:

- There may be a possibility of occurrence of kidney disease among hypertensive patients

Keywords : Estimation, Selected kidney function test, Screening.

Conclusion: Following the end of data gathering, the statistical analysis will be used to develop conclusions.

Introduction:

The kidneys create urine by filtering excess water and wastes from the blood. Kidney disease occurs when the kidneys become damaged and unable to filter the blood properly. A kidney disease, also known as renal disease or nephropathy, is an injury to or disease of the kidney. If a person has renal failure, he or she is at a higher risk for kidney disease, which can be treated with a kidney transplant or dialysis. Acute renal damage, kidney cysts, kidney stones, and kidney infections are examples of other kidney issues. Nephritis is an inflammatory kidney illness that comes in a variety of forms depending on where the inflammation occurs. Nephrosis is a kidney condition that is not inflammatory. Nephrosis and nephritis are two conditions that affect the kidneys.

Rationale of study:

Increased or decreased levels of each of the kidney function test can signify a variety of issues, not just health problems. Apart from kidney problems, elevated creatinine levels can be caused by intense exercise, eating cooked meat, or taking protein supplements. As a result, when interpreting the tests, these characteristics are also taken into account. Additional testing are carried out to confirm any health issues.³ Therefore the investigator wants to take a urine and blood samples, which include hypertensive patients, in which the investigator will do the kidney function test among hypertensive patients to look out the risk of occurrence of kidney disease and to determine the prevalence rate of kidney disease among hypertensive patients.

Methodology:

- First meeting: investigator will introduce herself with purpose of meeting.
- Written consent (if willing) and filling form of demographic data by patient/investigator.
- The investigator will make a planning for urine and blood samples collection
- The investigator will take the blood and urine samples from the hypertensive patients
- The samples will be send out for the investigation in laboratory
- The investigation reports will be collected from the laboratory
- The analysis of the data collection will be done

Inclusion Criteria:

- People who were willing to participate in this study
- Both male and female participants

Exclusion criteria:

- People who were not present at the time of data collection
- People who are not willing to participate in this study

Withdrawal Criteria - Participants who fulfil the following criteria will be withdrawn from the study:

1. Want to withdraw from the present study.
2. Not fulfilling study schedule.
3. Impaired memory due to chronic condition.

Sample size:

Cohran's formula fir sample size (india prevalence rate)

$$N = \frac{Z_{\alpha/2}^2 \times P(1-P)}{e^2}$$

where

$Z_{\alpha/2}$ as the level of significance at 5%

i.e, confidence interval =1.96

P = prevalence rate of hypertension in india in 2018 = 29.8% = 0. 298

D = desired error of margin = 7% = 0.07

$$N = \frac{1.96^2 \times 0.298 \times (1 - 0.298)}{0.07^2}$$

$$\equiv \frac{1.14 \times 0.702}{0.0049}$$

$$\equiv \frac{0.80028}{0.0049}$$

$$\equiv 163.2$$

$$\equiv 164 \text{ samples}$$

Interventions:

1. Section I: Demographic data of hypertensive patients
2. Section II : collection of blood and urine samples for investigation

Outcome measures:

Primary outcome: To evaluate the kidney function test by using serum creatinine, blood urea nitrogen and uric acid among hypertensive patients.

1. To determine the prevalence of kidney disease among hypertensive patients

2. Secondary outcome: To evaluate the kidney function test by using serum creatinine, blood urea nitrogen and uric acid among hypertensive patients

The time points of evaluation is showed in table no. 1

Data management and monitoring: The demographic data for patient: Name, Age, Sex.

Statistical analysis – analytical (mean, mean percentage, standard deviation) Inferential, Comparative statistics (student's test) and co-relational statistics is plan for data analysis.

Ethics and dissemination- Present study approved by the IEC (Institutional Ethics Committee) of DMIMS (DMIMS (DU)/IEC/2020-21/283). all participants will ask to read and sign the informed consent. The study results will be disseminate to study participants and published in peer-reviewed publications.

Expected Outcomes/Results:

- There may be a possibility of occurrence of kidney disease among hypertensive patients

Discussion:

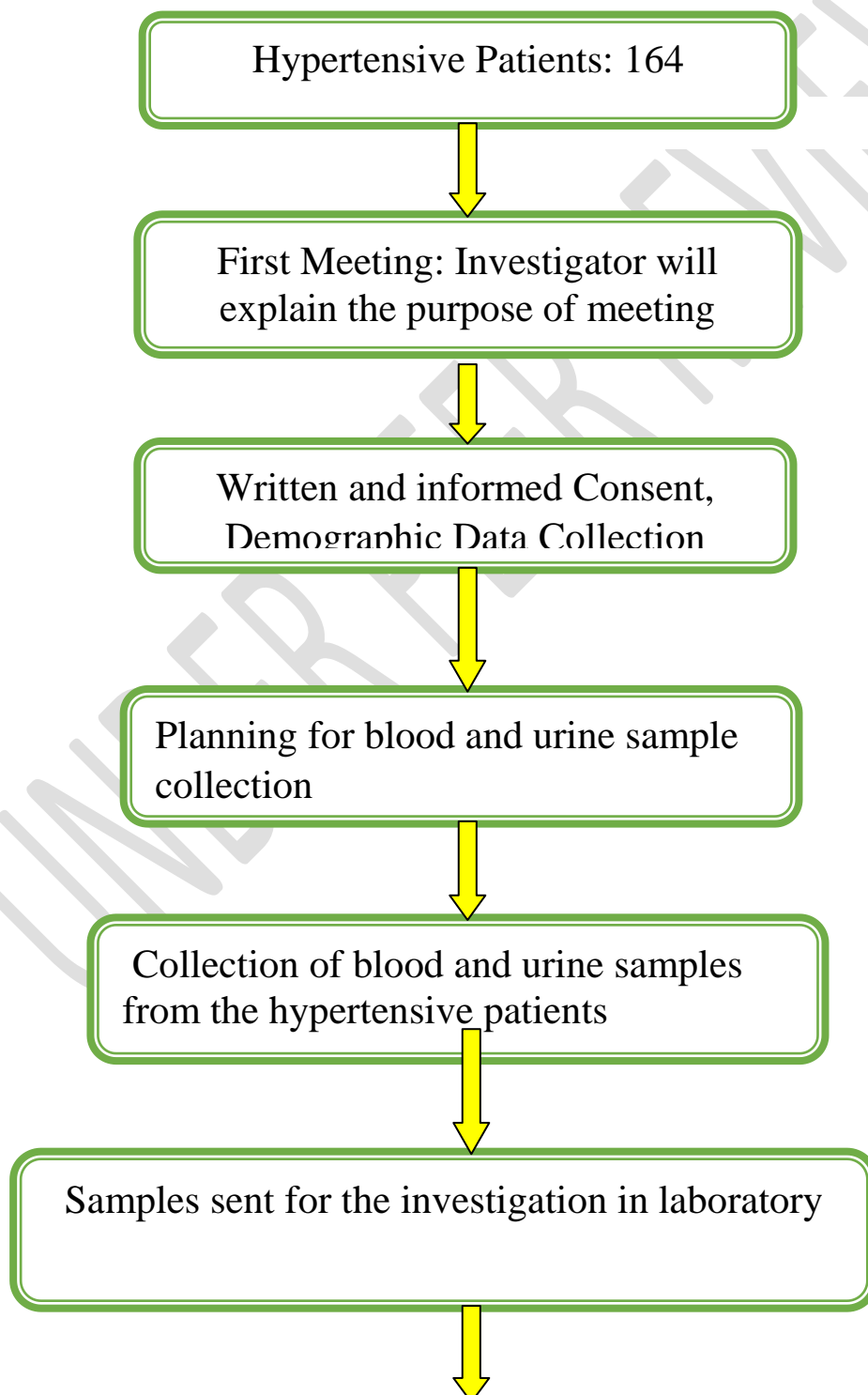
In Addis Ababa, Ethiopia, a cross-sectional study on Assessment of serum electrolytes and kidney function test for screening of chronic kidney disease was undertaken among Ethiopian Public Health Institute staff members in 2018. According to the MDRD and CKD-EPI equations, 3.6 and 1.9 percent of the study participants had CKD stage II, respectively. Hyperkalemia (serum potassium level > 5.0 mmol/L) and hypocalcemia (serum calcium level 2.15 mmol/L) were seen in 9.5 percent of the study individuals. An older age ($P = 0.006$), a high BMI ($P = 0.045$), and a history of CVDs ($P = 0.033$) were all found to be linked with a lower glomerular filtration rate. 9 per cent consumers³.

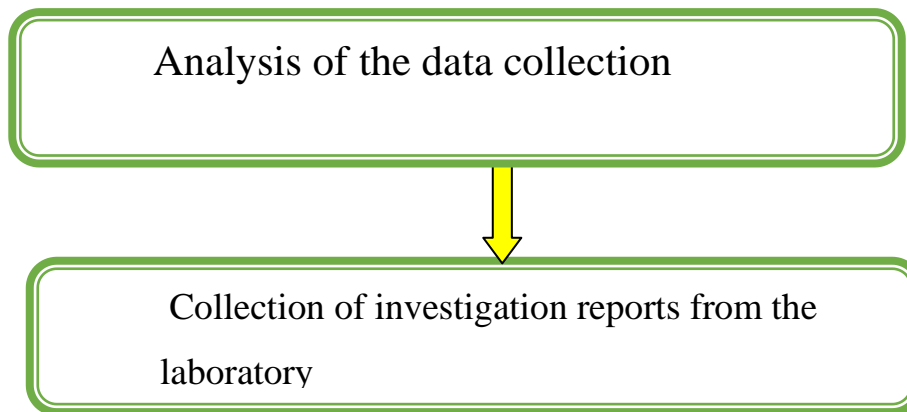
Estimation of serum creatinine, serum urea, glomerular filtration rate, and proteinuria among seemingly healthy persons was studied in a cross-sectional study to examine renal impairment and its relationship with BMI. The current investigation enlisted the participation of 100 healthy individuals, 48 males and 52 females. They discovered that the obese subgroup had the highest number of subjects (34 percent). The prevalence of low eGFR was found to be 3% among the individuals, as was the prevalence of chronic kidney disease (CKD) at 3%. They came to the conclusion that there was a total of 3% prevalence of renal failure among adults, with 2% of these being obese individuals..

Conclusion: Conclusion will be drawn from the statistical analysis after completion of data collection.

Figure and tables:

Figure: 1. Schematic Presentation of Plan of Work





References

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