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Sparing confirmatory testing in primary aldosteronism: the combination of renin, aldosterone and potassium levels

Submission date
13/08/2023

Recruitment status
No longer recruiting

Registration date
16/08/2023

Overall study status
Completed

Last Edited
24/06/2024

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Primary aldosteronism is a condition where the body produces too much aldosterone, a hormone that controls salt and water balance. The diagnosis process includes several steps: first, identifying potential cases through testing, then confirming the cases, and finally categorizing the specific subtype. Sometimes, in specific situations where there's low potassium, very low renin levels, and high PAC (aldosterone concentration), further tests might not be needed. However, the evidence for this is not very strong.

This study aimed to assess a simpler way to confirm primary aldosteronism without needing additional tests. It did this by looking at how well different predefined levels of PAC, along with suppressed renin and low potassium, can accurately diagnose the condition.

Who can participate?
Participants aged 18 years and above who underwent saline infusion test between January 2010 and March 2024 will be included.

What does the study involve?
A retrospective electronic chart review.

What are the possible benefits and risks of participating?
None.

Where is the study run from?
St. Luke's Medical Center-Quezon City (Philippines).

When is the study starting and how long is it expected to run for?
January 2022 to March 2024

Who is funding the study?
Investigator initiated and funded.

Who is the main contact?
Dr. Albert Macaire C. Ong Lopez, albertmacaireonglopez@outlook.com

Contact information

Type(s)
Principal investigator

Contact name
Dr Albert Macaire Ong Lopez

ORCID ID
https://orcid.org/0000-0003-4889-3226

Contact details
St. Luke's Medical Center - Quezon City
Section of Endocrinology, Diabetes and Metabolism
279 E Rodriguez Sr. Ave
Quezon City
Philippines
1112
+63 (02)8723 0101
albertmacaireonglopez@outlook.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
SL-22004

Study information

Scientific Title
Sparing Confirmatory Testing In Primary Aldosteronism (SCIPA): A Multicenter Retrospective Diagnostic Accuracy Study

Acronym
SCIPA

Study objectives
A hypertensive patient with screening results of baseline plasma aldosterone concentration > 15 ng/dL, suppressed plasma renin activity and spontaneous hypokalemia confirms primary aldosteronism disease and may not do dynamic testing

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 14/02/2022, St. Luke's Institutional Ethics Review Committee (IERC) (279 E Rodriguez Sr. Ave, Quezon City, 1112 Metro Manila, Quezon City, 1112, Philippines; +63 87230101; ethicsreview@stlukes.com.ph), ref: SL-22004

Study design
Multicenter retrospective diagnostic accuracy cohort-selected cross-sectional study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Primary aldosteronism

Interventions
Baseline clinical and laboratory data will be retrieved from eligible patients who underwent saline suppression testing via the electronic medical records. The saline suppression test will serve as the reference standard which is used to confirm the presence or absence of primary aldosteronism disease.

The initial screening laboratory blood exams shall include the baseline plasma renin activity, baseline plasma aldosterone concentration, and serum potassium level. Other data such as abdominal CT-scan findings and other surgical and/or histopathology results will likewise be obtained.

The index test to be evaluated comprises the combination of baseline plasma aldosterone concentration (PAC) at different pre-specified cutoffs points (> 10, >15, >20, & >25 ng/dL), with suppressed baseline plasma renin activity (PRA) (at least less than 1.0 ng/mL/hr) and presence of spontaneous hypokalemia.

For the saline infusion test protocol, patients remained in supine position for at least 1 hour prior to saline infusion. Samples of plasma aldosterone and serum potassium were drawn at baseline. Afterwards, 0.9% sodium chloride were infused at rate of 500 ml per hr over 4 hours for a total of 2 liters. At the end of infusion, repeat plasma aldosterone and serum potassium were extracted. A positive test result is defined as post saline-infusion plasma aldosterone levels of >10 ng/dL or a decrease of <50% of the post-saline infusion plasma aldosterone.

Intervention Type
Other

Primary outcome(s)
Aldosterone elevation, plasma renin activity, and hypokalemia obtained at baseline ("screening values')
through electronic health records.

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
31/03/2024

Eligibility

Key inclusion criteria
Current inclusion criteria as of 21/06/2024:
Patients above 18 years of age who underwent saline infusion test between January 2010 and March 2024 will be included in this study.

Previous inclusion criteria:
Patients above 18 years of age who underwent saline infusion test between January 2010 and July 2023 will be included in this study.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
133

Key exclusion criteria
Those who did not complete the saline infusion test or did not comply with the saline infusion protocol will be excluded

Date of first enrolment
01/01/2010

Date of final enrolment
31/03/2024

Locations

Countries of recruitment
Philippines

Study participating centre
St. Luke's Medical Center-Quezon City
279 E Rodriguez Sr. Ave
Quezon City
Philippines
1112

Study participating centre
St. Luke's Medical Center-Global City
Block 16 Lot 7, Crescent District
Rizal Drive corner 32nd Street
Bonifacio Global City
Taguig City
Philippines
1634

Study participating centre
Makati Medical Center
No. 2 Amorsolo Street
Legaspi Village
Makati City
Philippines
1229

Sponsor information

Organisation
St. Luke's Medical Center

ROR
https://ror.org/02h4kdd20

Funder(s)

Funder type
Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr Albert Macaire C. Ong Lopez (albertmacaireonglopez@outlook.com)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			04/09/2023	No	No
Basic results		21/06/2024	21/06/2024	No	No
Protocol file	version 3	14/10/2022	16/08/2023	No	No