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

Submission date 13/08/2023	Recruitment status No longer recruiting	Prospectively registered[X] Protocol
Registration date 16/08/2023	Overall study status Completed	 [] Statistical analysis plan [X] Results
Last Edited 24/06/2024	Condition category Nutritional, Metabolic, Endocrine	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.

Contact information

Type(s) Principal Investigator

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number Nil known

Secondary identifying numbers 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

Secondary study design Cross sectional study

Study setting(s) Hospital

Study type(s) Diagnostic

Participant information sheet Not applicable (retrospective study)

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 measure

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

Secondary outcome measures There are no secondary outcome measures

Overall study start date 04/01/2022

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

Age group Adult

Lower age limit 18 Years

Sex

Both

Target number of participants 157

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

Sponsor details 279 E Rodriguez Sr. Ave Quezon City Philippines 1112 +63 87230101 ethicsreview@stlukes.com.ph

Sponsor type Hospital/treatment centre

Website https://www.stlukes.com.ph/

ROR https://ror.org/02h4kdd20

Funder(s)

Funder type Other

Funder Name Investigator initiated and funded

Results and Publications

Publication and dissemination plan Planned publication in a high-impact peer-reviewed journal

Intention to publish date 01/07/2024

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?
<u>Protocol file</u>	version 3	14/10/2022	16/08/2023	No	No
Basic results			04/09/2023	No	No
Basic results		21/06/2024	21/06/2024	No	No