

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

<b>Submission date</b> 13/08/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 16/08/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/06/2024	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> 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 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](mailto: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](mailto:albertmacaireonglopez@outlook.com)

## Additional identifiers

### Clinical Trials Information System (CTIS)

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?
<a href="#">Basic results</a>			04/09/2023	No	No
<a href="#">Basic results</a>		21/06/2024	21/06/2024	No	No
<a href="#">Protocol file</a>	version 3	14/10/2022	16/08/2023	No	No