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Algorithm to predict blood pressure therapy

Submission date 17/03/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 19/03/2025	**Overall study status** Ongoing	
Last Edited 03/04/2025	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
High blood pressure is common in New Zealand and can lead to serious health problems like strokes and heart attacks. There are four main types of drugs used to treat high blood pressure, which affect the heart, kidneys, and blood vessels. Finding the right drug or combination of drugs is often a trial-and-error process, which can take many months or even over a year, leaving patients at risk during this time. This pilot study aims to test a new algorithm that uses genetic information from 14 genes related to blood pressure control to help choose the right drug more quickly. DNA will be collected from cheek swabs to see if the algorithm can make better drug choices based on patients' history of blood pressure response to different drugs.

Who can participate?
Participants with a diagnosis of hypertension for at least 1 year and up to 5 years who are attending Auckland-based GP practices involved in the study.

What does the study involve?
After providing written informed consent, volunteers will visit their GP practice to have two cheek swabs taken. Researchers will then review their medical records to gather demographic information and details about their history with blood pressure medications.

What are the possible benefits and risks of participating?
This study could help save time for both patients and GPs by finding the right blood pressure medication more quickly, potentially reducing healthcare costs and improving patient outcomes. As this is a pilot study, there may be unknown risks, but the process involves standard medical procedures like cheek swabs and chart reviews.

Where is the study run from?
University of Auckland (New Zealand)

When is the study starting and how long is it expected to run for?
March 2025 to April 2027

Who is funding the study?
The study is funded by the inaugural Partridge Family Research Laureate award (New Zealand)

Who is the main contact?
Prof Julian Paton (j.paton@auckland.ac.nz)

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
EXP 2025 21826

Study information

Scientific Title
Association between a pharmacogenomic algorithm to predict blood pressure therapy with blood pressure response to anti-hypertensive therapy: a retrospective pilot study

Study objectives
The specific aims of the pilot study are to:
1. Review blood pressure history together with prescribed medications noting efficaciousness of drugs used and time to control blood pressure in primary care patients with hypertension.
2. Obtain mouth swab samples for isolation of DNA from primary care patients with hypertension.

3. Determine if known single nucleotide polymorphisms on 11 genes related to blood pressure predict the most efficacious blood pressure lowering medication in patients with hypertension

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 25/03/2025, Health and Disability Ethics Committee (Ministry of Health, 133 Molesworth Street, Wellington, 6011, New Zealand; -; hdecs@health.govt.nz), ref: EXP 2025 21826

Study design
Multi-centre retrospective observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
GP practice

Study type(s)
Treatment, Efficacy

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Hypertension

Interventions
This is a retrospective study of patient records. Clinic blood pressure measured using a non-invasive brachial artery blood pressure device. Patient notes will be reviewed for information regarding number and types of medications needed to control blood pressure, time to control, number of clinic visits to control, side effects from hypertension therapy, hypertension associated adverse events during treatment. Mouth swab samples will be obtained for isolation of DNA and identification of single nucleotide polymorphisms on 11 genes related to blood pressure.

Intervention Type
Other

Primary outcome measure
Clinic blood pressure measured using a non-invasive brachial artery blood pressure device (e.g., oscilometric, auscultation) will be obtained by reviewing patient notes.

Secondary outcome measures

Obtained by reviewing patient notes:
1. Number and types of medications needed to control blood pressure
2. Time to control
3. Number of clinic visits to control
4. Side effects from hypertension therapy
5. Hypertension associated adverse events during treatment
6. Single nucleotide polymorphisms on 11 genes related to blood pressure will be determined from mouth swab samples

Overall study start date
17/03/2025

Completion date
30/04/2027

Eligibility

Key inclusion criteria
1. Participant is able and willing to provide informed consent.
2. Participant is ≥20 and ≤50 years of age.
3. Participant with diagnosis of Hypertension for a minimum of 1 year and up to 5 years.
4. Participant has been on the same class/classes of blood pressure medication for a minimum of 6 months.
4.1. Note: A change in dosage, frequency, or specific medication is acceptable as long as there have been no changes to the class/classes of medications prescribed.
5. Participant is currently prescribed and taking one of the following classes of medications alone or in combination with each other:
5.1. Diuretics (thiazide or thiazide-like)
5.2. ACE Inhibitors
5.3. Angiotensin Receptor Blocker (ARB)
5.4. Beta-blockers
5.5. Ca2+ Channel Blockers
6. Evidence that the participant has regular GP visits and is compliant with medication (i.e., collects prescriptions).

Participant type(s)
Patient

Age group
Adult

Lower age limit
20 Years

Upper age limit
50 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Participant has a diagnosis of secondary hypertension or is pregnant.
2. Participant is currently prescribed and taking any additional class of medication(s) for high blood pressure not included in the list above
3. Participant has Systolic blood pressure >190 or Diastolic blood pressure >120 documented within the six months prior to visit.
4. Participant has co-morbidities such as heart failure, myocardial infarction and renal impairment.
5. Any other reason that the participant is inappropriate for study enrolment in the opinion of the Investigator.

Date of first enrolment
01/05/2025

Date of final enrolment
30/04/2027

Locations

Countries of recruitment
New Zealand

Study participating centre
Remuera Village Medical Centre
597 Remuera Rd, Remuera
Auckland
New Zealand
1050

Study participating centre
Meadowbank Medical Centre
2 Blackett Cres, Meadowbank
Auckland
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1072

Sponsor information

Organisation
University of Auckland

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Sponsor type
University/education

Website
https://www.auckland.ac.nz/en.html

ROR
https://ror.org/03b94tp07

Funder(s)

Funder type
Charity

Funder Name
Partridge Family Research Laureate award

Results and Publications

Publication and dissemination plan
Publication of study results in high-impact scientific journal

Intention to publish date
01/05/2028

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof Julian Paton (j.paton@auckland.ac.nz)

IPD sharing plan summary
Available on request