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Patient self-management of blood pressure to improve outcomes for people with Immunoglobulin A (IgA) nephropathy

Submission date
14/11/2025

Recruitment status
Recruiting

Registration date
18/11/2025

Overall study status
Ongoing

Last Edited
18/12/2025

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
IgA nephropathy is a kidney condition in which an imbalance in the patient's immune system causes injury to the tiny filters within their kidneys leading to leakage of protein and blood into the urine, and decreased kidney function. Because IgA nephropathy tends to occur when patients are young, they have a high risk of developing kidney failure over their lifetime. Controlling blood pressure (BP) can protect their kidney filters from further injury. When done well, this treatment can help reduce the amount of protein in the urine (the best marker of kidney damage) and preserve kidney function. Despite the importance of BP control, there is no accepted standard for how BP should be measured and treated in patients with IgA nephropathy. By checking BP only at clinic visits, there are missed opportunities to detect and treat high BP appropriately. This study aims to test whether patients with IgA nephropathy who self-manage their BP will have better BP control and less protein in their urine compared to patients whose BP is measured and treated only at kidney clinic visits.

Who can participate?
Adult patients with a diagnosis of IgA nephropathy confirmed on a kidney biopsy who have a moderate amount of protein in their urine (at least 0.5 grams per day) and whose blood pressure is above 130/85 mmHg in the clinic will be invited to participate.

What does the study involve?
Self-management means that patients measure their BP at home and adjust the dose of their medications to a target BP value. A previous clinical trial conducted in patients without kidney disease showed that patients and their family doctors were able to successfully develop a self-management protocol. Working with our patient partners, we have adapted that protocol for patients with IgA nephropathy. The next step is to conduct a pilot clinical trial involving approximately 25 patients with IgA nephropathy who attend kidney clinics in Ottawa and Vancouver. Trial participants will be randomly chosen to either manage their BP using the self-management protocol or to be in the control group. Participants in the self-management group will be taught how to accurately measure their BP at home over a 7-day period each month. If most of these BP values are above target, they will contact the clinic for a new medication

prescription based on a 3-step plan which was developed with their doctor. Participants in the control group will have their BP measured and treated at clinic visits only. All participants will be followed for 6 months. At the end of the study period, we will measure BP and urine protein levels in all participants and compare these between the self-management and control groups. We will also interview participants in the self-management group to ask them about their experiences. The main outcome of the pilot trial is to find out if patients with IgA nephropathy will be willing to enter a trial of self-management of BP and to ensure that the protocol can be implemented safely and is not overly burdensome. The trial will also get preliminary information about whether self-management leads to better BP control and less protein in the urine.

What are the possible benefits and risks of participating?
The self-management intervention may or may not directly benefit participants. Participants who self-manage their BP may be at higher risk of experiencing low blood pressure or an abnormal blood test such as potassium due to more rapid escalation of BP medications. The chances of this happening are expected to be low based on experience from previous similar studies.

Where is the study run from?
The study will be conducted at Glomerulonephritis clinics at The Ottawa Hospital (Ottawa, Ontario, Canada) and Vancouver General Hospital (Vancouver, British Columbia, Canada).

When is the study starting and how long is it expected to run for?
The study will start in December 2025. Participants will be followed for six months. The study is expected to finish in June 2027.

Who is funding the study?
The study has received funding from the Kidney Foundation of Canada.

Who is the main contact?
Dr. Mark Canney, a kidney specialist and researcher at The Ottawa Hospital, is the principal investigator of the study and will serve as the main contact for all study related issues.

Contact information

Type(s)
Public, Principal investigator

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Additional identifiers

Protocol serial number
24KHRG-1257044

Study information

Scientific Title
Self-Management to Achieve Reduction in proTeinuria in patients with IgA nephropathy

Acronym
SMART-IgAN

Study objectives
The primary objective of this pilot study is to determine the feasibility of a full-scale trial by showing that self-management of blood pressure is acceptable to patients and achievable in the clinic setting. The primary objective of the full-scale trial is to compare the achieved blood pressure values between patients randomized to self-management and patients randomized to usual care.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 09/10/2025, Ottawa Health Science Network Research Ethics Board (Civic Box 675, 725 Parkdale Avenue, Ottawa, K1Y 4E9, Canada; +1 (613)798-5555 ext 16719; REBAdministration@ohri.ca), ref: 20250424-01H

Study design
Multicenter interventional open-label pilot randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Blood pressure control in patients with IgA nephropathy

Interventions
Participants will be randomized 2:1 to self-management (intervention) or usual care (comparator), carried out with a web-based randomization system. Participants in the intervention and control group will be assessed in the clinic at baseline, at 3 months and at 6 months. In both groups, the dose of renin-angiotensin-aldosterone-system (RAAS) inhibitor will be progressively increased to achieve a systolic BP <120 mmHg. The use of other anti-hypertensive medications will be permitted in both groups at the discretion of the treating physician after the dose of RAAS inhibitor has first been maximized.

Intervention group
Participants randomized to self-management will receive training in home BP measurement and adjustment of anti-hypertensive medications according to a pre-specified plan. They will be asked to measure their BP twice daily (morning and evening) for 7 consecutive days at the beginning of each month (measurement week). Each measurement will include 3 values taken 1 minute apart after 5 minutes of rest. The average of values 2 and 3 will be recorded as the BP for that measurement. A complete week of measurements will therefore encompass 14 BP values (7 morning and 7 evening values). An instruction sheet will be provided to each participant to explain what should be done based on their BP values. Each participant will have an individualized three-step treatment plan that is developed with their physician, and which is based on their recorded home BP values during the measurement week of each month. Participants who record 50% or more values above target during their measurement week will move to the next step of their treatment plan by contacting their physician for a new medication prescription. In this way, there is no requirement for an additional clinic encounter. Once the three steps have been completed, the participants will return to the clinic to create a new three-step plan.

Control group
Participants randomized to usual care (control group) will be asked to attend their scheduled clinic visit with their nephrologist for monitoring and treatment of their blood pressure. The physician who assessed them in the clinic will be notified to ensure that any planned changes to anti-hypertensive medications from their clinic visit are actioned.

The randomization website will be managed by the Data Management Services of the Ottawa Methods Centre Ottawa Hospital Research Institute. Randomization will be stratified by site (Ottawa versus Vancouver).

Intervention Type
Other

Primary outcome(s)
The primary outcome of the pilot trial will be feasibility defined as achieving target threshold for both recruitment and study completion. The study protocol will be revised based on adherence metrics and participant feedback as detailed below:
1. The probability of successful recruitment will be calculated as the percentage of eligible participants who are randomized. A threshold of >50% will be required for progression to a full-scale trial.
2. The probability of retention will be calculated as the percentage of randomized patients who

complete the study. A threshold of >80% will be sought for progression to a full-scale trial.
3. Adherence to the self-management protocol will be quantified for each patient in the intervention group using the median number of recorded home BP readings per measurement week. Adherence will be further explored from participant feedback in longitudinal diary entries and a semi-structured interview. There is no progression criterion for adherence but the study protocol for a future full-scale trial will be refined based on these factors.

Key secondary outcome(s))
Efficacy outcomes will be assessed on an exploratory basis only:
1. Mean difference in achieved BP between the groups using automated office BP measurement at the end of the study period
2. Difference in systolic BP from baseline to 6-month follow-up using an automated office BP measurement
3. Difference in diastolic BP from baseline to 6-month follow-up using an automated office BP measurement
4. Difference in percentage proteinuria reduction from 24-hour between the groups using 24-hour urine collections from baseline to 6 months
5. Proportion of patients who achieve an absolute reduction in proteinuria to less than 0.5 g/day using 24-hour urine collections at the 6-month visit
6. Change from baseline in exercise (using a self-completion questionnaire), 24-hour urinary sodium excretion (using 24-hour urine collection) and waist circumference (measured at clinic visit) at the 6-month visit

Completion date
30/06/2027

Eligibility

Key inclusion criteria
1. Adult patients aged ≥18 years who provide written informed consent
2. Biopsy-confirmed diagnosis of IgA nephropathy
3. Proteinuria > 0.5 g/day quantified from 24-hour urine collection or urine protein:creatinine ratio >50 mg/mmol or urine albumin:creatinine ratio >30 mg/mmol
4. Clinic systolic BP >130 mmHg or diastolic BP >85 mmHg (automated office BP measurement)
5. Willing to self-manage BP

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Currently receiving immunosuppression or in need of urgent start immunosuppression (e.g., rapidly progressive glomerulonephritis or nephrotic syndrome)
2. Kidney failure defined by the need for dialysis, kidney transplantation or eGFR <15 mL/min
3. Recent (within 3 months) history of acute myocardial infarction or stroke
4. Heart failure with reduced ejection fraction
5. Concomitant diabetic nephropathy on kidney biopsy
6. Pregnancy (or actively planning a pregnancy) or breastfeeding
7. Life expectancy <12 months
8. Allergy or intolerance to both an angiotensin converting enzyme inhibitor and angiotensin II receptor blocker
9. Severe hypertension requiring urgent treatment (>180/100 mmHg)

Date of first enrolment
05/01/2026

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
Canada

Study participating centre
The Ottawa Hospital
1967 Riverside Drive 5th floor
Ottawa
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Study participating centre
Vancouver General Hospital
2775 Laurel Street 5th floor
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Sponsor information

Organisation
Ottawa Hospital Research Institute

ROR
https://ror.org/05jtef216

Funder(s)

Funder type
Not defined

Funder Name
Kidney Foundation of Canada

Alternative Name(s)
La Fondation canadienne du rein, The Kidney Foundation of Canada, Kidney Foundation, kidneycanada, KFOC

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2	24/09/2025	18/11/2025	No	No