ISRCTN12374636 https://doi.org/10.1186/ISRCTN12374636

Improving the health of veterans with chronic kidney disease

Submission date
25/02/2022

Recruitment status
No longer recruiting

Registration date
15/03/2022

Overall study status
Completed

Last Edited
23/02/2024

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims:
Sodium glucose co-transport 2 inhibitors (SGLT2i) are a class of drugs approved for the treatment of type 2 diabetes. Numerous studies have been published showing SGLT2i improves outcomes in chronic kidney disease (CKD) patients. CKD means your kidneys are damaged and can't filter blood the way they should. The main risk factors for developing kidney disease are diabetes, high blood pressure, heart disease, and a family history of kidney failure. The aim of this study is to improve the health of veterans with CKD by evaluating the effectiveness of a targeted pharmacy intervention in improving the rate of SGLT2i initiation among eligible patients.

Who can participate?
Veterans with chronic kidney disease who are candidates for SGLT2i therapy. These patients will be identified through an existing dashboard created by the VA.

What does the study involve?
Eligible patients will be mailed a letter outlining the benefits of starting SGLT2i therapy. Then, a care team member will contact the patient and offer a pharmacy consultation to initiate the medication. After reviewing criteria and discussing the risks and benefits with the Veteran, the pharmacist will initiate the appropriate dose of SGLT2i. Notification of the drug change will be sent to the patient’s primary care provider. The pharmacist will schedule follow up labs 3 months after drug initiation and provide a phone number to Veterans to contact the pharmacist for future questions or to report adverse events. Labs at 3 months will be reviewed by the program’s medical assistant. The Veteran will be contacted by letter with a summary of their lab results (sent by medical assistant) and reminded of the contact number. Any issues with labs will be flagged to the pharmacist to be addressed with the Veteran.

What are the possible benefits and risks of participating?
Benefits include improved CKD, cardiovascular, and other health outcomes, as well as decreased mortality. In trials, the incidence of hypoglycemia or other adverse events did not differ between SGLT2i treatment and control arms. Risks include any potential adverse events to SGLT2i, such as diabetic ketoacidosis, urinary tract infections, etc.

Where is the study run from?
The Minneapolis VA Health Care System (USA)

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

Who is funding the study?
US Veterans Association (USA)

Who is the main contact?
Areef Ishani, MD, Areef.Ishani@va.gov

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Evaluating the implementation of targeted pharmacy services to enhance the uptake of SGLT2i among veterans with chronic kidney disease (CKD)

Study objectives
Patients that receive a targeted pharmacy intervention will have higher rates of SGLT2i initiation than those receiving usual care

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/01/2022, Minneapolis VA Health Care System (1 Veterans Dr, Minneapolis, MN, 55417, USA; +1 612-467-5655; julie.toth@va.gov), ref: n/a

Study design
Multicenter interventional non randomised study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Chronic kidney disease

Interventions

Using an established VA dashboard that identifies chronic kidney disease patients that are candidates for SGLT2i therapy, half of eligible patients will be sent a letter informing them of the benefits of this medication (the letter will be sent to patients whose social security number ends with an odd digit). A medical assistant will then reach out to those patients and offer to schedule a consultation with one of two intervention pharmacists. The pharmacist will review the patients' charts and ensure they meet necessary criteria for initiating the drug and no exclusion criteria exist. After reviewing criteria and discussing the risks and benefits with the Veteran, the pharmacist will initiate the appropriate dose of SGLT2i. Notification of the drug change will be sent to the patient's primary care provider. The pharmacist will schedule follow up labs 3 months after drug initiation and provide a phone number to Veterans to contact the pharmacist for future questions or to report adverse events. Labs at 3 months will be reviewed by the program's medical assistant.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
SGLT2 inhibitors

Primary outcome(s)
SGLT2i initiation will be tracked quarterly by assessing the presence of SGLT2 inhibitors on active medication lists in the electronic health record

Key secondary outcome(s))
1. Reach: Proportion of eligible patients being reached in each intervention assessed quarterly by data collected through the tracking app that has been developed to monitor patient outreach
2. Fidelity: Measured using an intervention tracking app assessed quarterly by data collected through the tracking app that has been developed to monitor patient outreach
3. Acceptability: Patient perception of starting the medication will be measured at the end of year one and the end of year two through semi-structured one-on-one qualitative interviews with patients

Completion date
01/01/2026

Eligibility

Key inclusion criteria
1. CKD (defined as eGFR >=25 and eGFR <60 x2)
2. Type 2 Diabetes (defined as either ICD9/10 code of Type 2 DM or most recent A1c >=7)
3. Must have active Metformin or (not on Metformin and has a Metformin allergy)

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Sex
All

Key exclusion criteria
1. Type 1 diabetes
2. Taking SGLT-2 or GLP-1
3. SGLT2 allergy
4. On dialysis
5. Have a diagnosis of Pancreatic Cancer or Pancreatitis

Date of first enrolment
01/03/2022

Date of final enrolment
01/01/2025

Locations

Countries of recruitment
United States of America

Study participating centre
Minneapolis VA Health Care System
1 Veterans Dr
Minneapolis
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55417

Sponsor information

Organisation
Minneapolis VA Health Care System

ROR
https://ror.org/02ry60714

Funder(s)

Funder type
Government

Funder Name
U.S. Department of Veterans Affairs

Alternative Name(s)
Department of Veterans Affairs, United States Department of Veterans Affairs, US Department of Veterans Affairs, U.S. Dept. of Veterans Affairs, Veterans Affairs, Veterans Affairs Department, VA, USDVA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		05/01/2024	08/01/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes