START trial: **S**GLT**2** inhibitors **A**s first line therapy to prevent **R**enal decline in **T**ype 2 diabetes

START
SGLT2 INHIBITORS AS FIRST LINE THERAPY TO IMPROVE RENAL FUNCTION IN TYPE 2 DIABETES

A community-based clinical trial testing a new first-line therapy among individuals recently diagnosed with type 2 diabetes.

The George Institute for Global Health

MONASH University

WHAT IS START?

START is a NHMRC-funded clinical trial that will evaluate the comparative effects of the Sodium Glucose Co-Transporter 2 (SGLT2) inhibitor dapagliflozin compared to metformin, on annual decline in eGFR, when used as first-line therapy in people with newly diagnosed type 2 diabetes.

By assisting with the identification of participants for the START trial, you could help to discover if SGLT2 inhibitors can reduce the risk of complications due to type 2 diabetes developing, such as kidney and heart problems, more than the currently recommended type 2 diabetes medication, metformin.

The intervention will be evaluated by a pragmatic, multi-centre, double-blind, randomised trial involving at least 60 primary health care practices across NSW, VIC and QLD. The sample size of 994 participants (497 intervention and 497 control groups) will detect a difference in eGRF slope between dapagliflozin and metformin over a 24-month period. Changes in urine albumin creatinine ratio, serum creatinine, HbA1c, fasting blood glucose, systolic and diastolic blood pressure, body weight, quality of life and symptoms of anxiety and depression will be monitored.

WHO IS ELIGIBLE TO PARTICIPATE?

Participant eligibility criteria for the START trial:

- ☑ Diagnosis of T2D within the last 4 years
- ☑ Aged ≥18 years
- ☑ BMI between 18.5 and 45 kg/m^2
- ☑ Drug naïve, or managed with metformin monotherapy and willing to be randomised to either dapagliflozin or metformin
- ☑ eGFR ≥30 ml/min/1.73m^2
- ☑ Signed informed consent

FOR MORE INFORMATION

Email: START-trial@georgeinstitute.org.au
Telephone: +61 2 8052 4343

WHO IS RUNNING THIS STUDY?

This study is being coordinated by The George Institute for Global Health and Monash University. The START trial's multi-disciplinary team is led by Professor Bruce Neal (Executive Director, The George Institute for Global Health, Australia), A/Professor Clare Arnott (Co-Director, Global Chronic & Complex Diseases, Cardiovascular Program and Heart Failure Program, The George Institute for Global Health), and Professor Sophia Zoungas (Head, School of Public Health and Preventive Medicine, Monash University).

WHAT ARE THE ADVANTAGES OF PARTICIPATING?

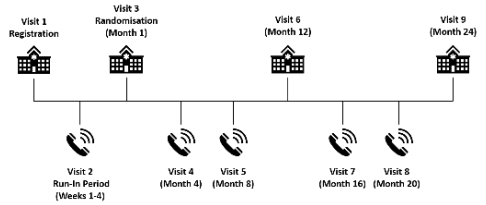
Participation in this study offers general practices the opportunity to participate in research as well as the potential to contribute towards improving the health of their patients with type 2 diabetes. Financial remuneration ($150 per randomised participant) will be provided to general practices to support any administrative costs that may arise.

WHAT IS REQUIRED BY THE GP PRACTICE?

The role of your GP practice in the START trial is minimal and there is no individual patient data collection required from you. We would like your assistance to identify potential participants who attend your GP practice who we can approach to participate in START. Our project team will fully coordinate the trial.

WHAT ARE THE TIMELINES?

START will commence recruitment in June /July 2022. Participants will attend follow-up every 16 to 20 weeks: four scheduled face-to-face and five remote (telephone or video call) visits over 108 weeks (i.e., 2 years and one month). Our project team will fully organise and coordinate these visits.



CPD Activity - RACGP

If you find your participation in the START trial as a co-investigator to be educational and valuable, you can self-record as a CPD activity and claim for 2 CPD points per hour using the 'Quick log' function on your myCPD dashboard (https://www.racgp.org.au/login).