

SCORED Clinical Trial (sanofi-aventis) – HCP Criteria
Principle Investigator: Dr. Ron Sigal, Sub Investigator: Dr. Vicky Parkins

OVERVIEW:

This trial is a randomized, double blind, placebo controlled study to demonstrate the effects of sotagliflozin, an SGLT2 and SGLT1 inhibitor, on cardiovascular and renal events in patients with T2DM who also have cardiovascular risk factors and moderately impaired renal function. This study is a Phase 3, CV outcomes trial.

PATIENT REQUIREMENTS:

- Total study duration is approximately 4 years, depending on the number of patient events
- After start-up visits, patients will be seen twice a year with phone calls in between clinical visits

INCLUSION CRITERIA:

- **T2DM with A1C $\geq 7.0\%$**
- **Estimated glomerular filtration rate ≥ 25 and ≤ 60 mL/min/1.73 m²**
- **Patient must meet 1 of the following 2 criteria:**
 - Age ≥ 18 years with at least one major cardiovascular (CV) risk factor
 - Hospitalization for HF in previous 2 years
 - Ejection fraction $\leq 40\%$
 - Left ventricular hypertrophy
 - BNP ≥ 400 pg/mL
 - Troponin ≥ 15 ng/L
 - In the absence of a major CV risk factor, age ≥ 55 years with at least 2 minor CV risk factors
 - BMI ≥ 35 kg/m²
 - LDL > 3.36 mmol/L **OR** HDL < 1.03 mmol/L for men or < 1.3 mmol/L for women
 - Currently smoking at least 1 cigarette a day
 - UACR between 3 and 34 mg/mmol
 - BP $> 140/90$ mmHg
 - Family history of coronary heart disease (MI or coronary revascularization) in first degree relative

Contact: CTU Research Coordinator, Amy Dunlop - 403-955-8119,
adtekron@ucalgary.ca

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