Determinants for Use of GLP-1 Receptor Agonists in Canada

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000001058

Study ID

1000001058

DARWIN EU® study

No

Study countries

Canada

Study description

Glucagon-like peptide-1 receptor agonists (GLP-1 RAs) are a class of medications which are either authorized for managing hyperglycemia in patients with type 2 diabetes mellitus (T2DM) or for weight management under

certain conditions in Canada. In recent years, there has been an increase in demand for these medications which led to a global shortage, affecting many countries including the European Union (EU) Member States and Canada. There have also been concerns about excessive off-label use for weight management in people without obesity or people with overweight who do not have weight related health problems, and this is intensifying the existing shortages with serious consequences for public health.

As part of a collaboration with the International Coalition of Medicine Regulatory Authorities (ICMRA), CNODES will replicate a study conducted by DARWIN EU (EUPAS1000000828). This study aims to describe characteristics of patients prescribed a GLP-1 RA and patterns of use between 2005 and 2025, including switching between substances and to other antidiabetic medications, as well as switching between selected brands.

The study will span over up to 10 years and will be conducted using routinely collected health data from 6 Canadian provinces. The primary analyses will be restricted to patients receiving GLP-1 RA prescriptions reimbursed through provincial public drug plans and the secondary analyses will be conducted using all available GLP-1 RA dispensations (in provinces with available data). We will estimate the monthly incidence and monthly point prevalence of prescriptions of GLP-1 RAs. We will characterize new users by the specified covariates. We will also describe the patterns of use including switching between substances and to other antidiabetics, as well as within-substance switching of strength.

Study status

Ongoing

Research institutions and networks

Institutions

Lady Davis Institute

First published: 01/02/2024

Last updated: 01/02/2024

Institution

University of British Columbia

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Last updated: 01/02/2024

Institution

University of Calgary, Calgary, Canada;

University of Manitoba, Winnipeg, Canada;

Dalhousie University, Halifax, Canada;

ICES, Toronto, Canada;

Saskatchewan Health Quality Council, Saskatoon, Canada

Networks

Canadian Network for Observational Drug Effect Studies (CNODES)

Canada

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Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Laurent Azoulay

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 16/03/2026

Study start date

Actual: 16/03/2026

Date of final study report
Planned: 14/05/2027

Sources of funding

- Other

More details on funding

CNODES is a collaborating core network partner of CoLab, which is funded for query-related activity by Canada’s Drug Agency (CDA-AMC, grant number C222 360).

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

Retrospective cohort study

Main study objective:

This study is a replication of a DARWIN EU study (EUPAS1000000828) using data from 6 Canadian provinces. The study has the following objectives:
1. To determine the incidence and prevalence of prescriptions of the GLP-1 RA medicines (overall, by ingredient, by brand [pre-defined]) during the last 10 years of available data, stratified separately by age, sex, indications (T2DM, obesity, weight management intent) [only for incidence] and prescriber specialty (where available) [only for incidence], and by calendar month in each of the provinces.
2. To characterize new drug users of GLP-1 RA medicines (overall and stratified by ingredient, by brand, by indication cohorts [T2DM, obesity, weight management intent]) by age, sex, highest strength, and a list of prespecified indications/comorbidities and related co-medications for each province. Characterization will be done over the whole study period and by calendar year.
3. To describe GLP-1 RA switching of substances (exenatide, liraglutide,

lixisenatide, dulaglutide, semaglutide, or tirzepatide cohorts) among new GLP-1 RA users for each province [overall study period] overall and by indication cohorts.
4. To describe GLP-1 RA within-substance switching of strength (limited to pre-defined cohorts of strength-levels, with brands when available, for liraglutide, dulaglutide, semaglutide, and tirzepatide) among new users of the respective medicine in each province [overall study period].
5. To describe GLP-1 RA switching of substances (exenatide, liraglutide, lixisenatide, dulaglutide, semaglutide or tirzepatide cohorts) among new GLP-1 RA users for each province between 2015–2020 and annually between 2021 and 2025, overall and by indication cohorts.
6. To describe GLP-1 RA within-substance switching of strength (limited to pre-defined cohorts of strength-levels, with brands when available, for liraglutide, dulaglutide, semaglutide, and tirzepatide) among new users of the respective medicine in each province between 2015–2020 and annually between 2021 and 2025.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

glucagon-like peptide-1 receptor agonists (GLP-1 RAs)

Study drug International non-proprietary name (INN) or common name

EXENATIDE

LIRAGLUTIDE

LIXISENATIDE

DULAGLUTIDE

SEMAGLUTIDE

TIRZEPATIDE

Anatomical Therapeutic Chemical (ATC) code

(A10BJ01) exenatide

exenatide

(A10BJ02) liraglutide

liraglutide

(A10BJ03) lixisenatide

lixisenatide

(A10BJ05) dulaglutide

dulaglutide

(A10BJ06) semaglutide

semaglutide

(A10BX16) tirzepatide

tirzepatide

(A10AE54) insulin glargine and lixisenatide

insulin glargine and lixisenatide

(A10AE56) insulin degludec and liraglutide

insulin degludec and liraglutide

Population studied

Short description of the study population

The study population will include all patients (≥ 66 years in Ontario) who received a dispensation for a GLP-1 RA between 2015 and 2025.

Age groups

- **Paediatric Population (< 18 years)**
- **Adult and elderly population (≥18 years)**

Study design details

Setting

We will be using routinely collected health data from 6 Canadian provinces (Nova Scotia, Ontario, Manitoba, Saskatchewan, Alberta, and British Columbia). The study period will be January 1, 2015, to December 31, 2025 (or the latest date of data availability in each province). To maintain consistency with the DARWIN EU study, the primary analyses will be restricted to patients receiving GLP-1 RA prescriptions reimbursed through provincial public drug plans. For these analyses, the study period will begin on September 1, 2019, corresponding to the earliest date that the first GLP-1 RA was added on the provincial formulary across provinces. In addition, secondary analyses will be conducted using all available GLP-1 RA dispensations, including publicly and privately reimbursed claims, as well as those paid out-of-pocket by patients. These analyses will be conducted for objectives 1 to 3 and 5 in all provinces except Ontario, where only public claims are captured.

In each province, the study population will include all individuals (≥ 66 years in Ontario) with a dispensation for a GLP-1 RA during the study period. For incident users (new users), a minimum of 365 days of data availability with no dispensation of the respective GLP-1 RA will be required. For objectives 3 and 5, no use of any GLP-1 RA in the prior year will be required. We will exclude

individuals with missing data on date of birth or sex.
The date of the GLP-1 RA dispensing (prevalent users) or first new dispensing of a GLP-1 RA (incident users) will be the cohort entry date. Follow-up will end at the earliest of: loss to follow-up, death, or end of the observation period (latest available data). Follow-up will additionally be censored when switching to another antidiabetic drug class or discontinuing not followed by another antidiabetic drug for objectives 3 and 5, and when discontinuing the specific GLP-1 RA ingredient for objectives 4 and 6.

Comparators

Not applicable

Outcomes

Not applicable

Summary results

Analyses will be completed in each provincial database and will be pooled across provinces where appropriate. We will estimate the monthly incidence and monthly point prevalence of prescriptions of GLP-1 RA with 95% confidence intervals, overall, by ingredient, and selected brands. We will describe new users' demographics, comorbidities, and other specified covariates. Characteristics will be summarized overall and stratified by ingredient, selected brands, and indication cohorts. We will describe the GLP-1 RA switching of substances and to other antidiabetics among new users of the respective medicine, by calculating the median time-to-switch and average time-on-treatment and provide Kaplan-Meier curves. Treatment trajectories will be represented using Sankey diagrams. Within-substance switching of strength will be similarly reported. Objectives 3 and 5 will be stratified by indication cohorts, and objectives 5 and 6 will be conducted subject to feasibility.

Documents

Study, other information

ICMRA GLP1 HMA-EMA Registration Appendix_2026.08.18.pdf (104.94 KB)

DARWIN EU study (EUPAS1000000828)

Link to project page on CNODES website.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s), other

Canadian provincial administrative health databases

Data sources (types)

Administrative healthcare records (e.g., claims)

Pharmacy dispensing records

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown