Database Linkage Study to Evaluate the Risk of Medullary Thyroid Carcinoma

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000513

Study ID

1000000513

DARWIN EU® study

No

Study countries

United States

Study status

Ongoing

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Nicole Kellier-Steele

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/03/2023

Actual: 31/03/2023

Study start date

Planned: 31/12/2025

Actual: 31/12/2025

Date of final study report

Planned: 31/03/2027

Study protocol

LY3298176 B014 NI PASS Protocol - Version 2_ENCePP_Redacted.pdf (1.86 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Other

Study topic, other:

Pharmacoepidemiology / Drug Safety and Risk Assessment

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Study design:

This is a database linkage study with an active comparator new user study design

Main study objective:

The primary objectives are to:

- estimate the incidence of MTC among adults (18 years of age and older) in the US (hereafter referred to as adult patients) who are exposed to LA GLP-1 RA therapies, as compared to adult patients initiating an active comparator medication using IRRs and 95% CIs, and
- characterize adult patients exposed to LA GLP-1 RA therapies, and active comparator cohorts using demographic and other clinical characteristics, including selected prescription medications dispensed during the baseline period, and duration of LA GLP-1 RA therapy use.

The secondary objective is to:

- evaluate trends in the annual incidence of MTC in adult patients in the US for identification of any possible increase related to the introduction of LA GLP-1 RA therapies, into the US market.

Study drug and medical condition

Medicinal product name

BYDUREON

VICTOZA

SAXENDA

TRULICITY

OZEMPIC

WEGOVY

RYBELSUS

MOUNJARO

Medicinal product name, other

Bydureon Bcise, Tanzeum, Zepbound

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

EXENATIDE

LIRAGLUTIDE

ALBIGLUTIDE

DULAGLUTIDE

SEMAGLUTIDE

TIRZEPATIDE

Anatomical Therapeutic Chemical (ATC) code

(A10BJ01) exenatide

exenatide

(A10BJ02) liraglutide

liraglutide

(A10BJ04) albiglutide

albiglutide

(A10BJ05) dulaglutide

dulaglutide

(A10BJ06) semaglutide

semaglutide

(A10BX16) tirzepatide

tirzepatide

Medical condition to be studied

Medullary thyroid cancer

Study design details

Comparators

T2D Active Comparator 1 Cohort:

- ≥1 dispensed prescription for any sodium-glucose transport protein 2 (SGLT2) or dipeptidyl peptidase IV (DPP-4) inhibitors during the study patient selection period.

T2D Active Comparator 2 Cohort:

- ≥1 dispensed prescription for any ADM, other than LA GLP-1 RA therapies, during the study patient selection period.

Overweight/obesity Active Comparator Cohort:

- ≥1 dispensed prescription for any AOM, other than LA GLP-1 RA therapies, during the study patient selection period.

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

IQVIA Longitudinal Prescription (LRx) Database, State Cancer Registries (SCRs), IQVIA Open Medical Claims (Dx), IQVIA PharMetrics® Plus (P+) Database

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

Not applicable