NN2211-8841 Database Linkage Study to Evaluate the Risk of Medullary Thyroid Carcinoma

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000001037

Study ID

1000001037

DARWIN EU® study

No

Study countries

United States

Study description

This is a database linkage study utilizing real-world data (RWD) to determine whether certain medicines used to treat type 2 diabetes (T2D) and support weight management (called GLP-1 RAs (Glucagon-like peptide-1 receptor agonists)) are linked to an increased risk of a rare cancer called medullary thyroid carcinoma (MTC). The purpose of this study is to compare how often medullary thyroid cancer occurs in people taking these medicines versus those taking other similar treatments. This study will use dispensed prescription claims and State Cancer Registry data to assess the risk of MTC.

Study status

Ongoing

Research institutions and networks

Institutions

Novo Nordisk

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Clinical Transparency (dept. 2834) Novo Nordisk A/S

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

Sources of funding

- Pharmaceutical company and other private sector

Study protocol

8841 protocol hma-ema redacted.pdf (11.84 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

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.
- 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 Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

BYDUREON

VICTOZA

SAXENDA

TRULICITY

OZEMPIC

WEGOVY

RYBELSUS

MOUNJARO

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

Population studied

Short description of the study population

All eligible patients must fulfill the following requirements:

- ≥18 years or older during the year of index (date of qualifying medication)
- In addition to index medication, ≥1 dispensed medication (any class) within 24 months prior to the index date1
- ≥1 dispensed medication (any class) after the index date and within 12 months of index date (12-month post-index period)
- No evidence of cohort qualifying medication during 12-month before the index date
- Reside in the US, including the District of Columbia (DC) during the study period
- No missing values for year of birth

Patient eligibility for inclusion by study cohorts, in addition to the above criteria are captured below.

LA GLP-1 RA therapies exposed cohort:

- ≥ 1 dispensed prescription for a LA GLP-1 RA therapy during the study patient selection period

T2D Active Comparator 1 Cohort:

- ≥1 dispensed prescription for 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 antidiabetic medication, other than LA GLP-1 RA therapies, during

the study patient selection period

Overweight/Obesity Active Comparator Cohort:

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

Patients with a diagnosis of MTC in the linked SCR data before their index date will not be included in the
study.

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

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Data sources (types)

Administrative healthcare records (e.g., claims)

Cancer registry

Drug prescriptions

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