Medullary Thyroid Carcinoma Surveillance Study: a Case-Series Registry (H9X-MC-B001)

First published: 03/05/2022

Last updated: 06/03/2025

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/45077

EU PAS number

EUPAS45076

Study ID

45077

DARWIN EU® study

No

Study countries

☐ United States

Study description

Please refer to EUPAS8759. This study is conducted in the US. The aim of the study is to monitor the number of annual new cases of medullary thyroid carcinoma (MTC) and to establish a registry of incident cases of MTC in adults in order to characterize their medical histories and possible risk factors, including history of treatment with long-acting GLP-1 receptor agonists.

Study status

Ongoing

Research institutions and networks

Institutions

United BioSource Corporation (UBC)

Switzerland

First published: 25/04/2013

Last updated: 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

Yuanyuan Wang

Study contact

yuanyuan.wang@lilly.com

Primary lead investigator

Yuanyuan Wang

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 19/01/2015

Study start date
Actual: 19/01/2015

Date of final study report
Planned: 31/12/2030

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company, Novo-Nordisk, AstraZeneca

Study protocol

MTC Case Series Registry Protocol_v8.0 dated 03Feb2022_Redacted.pdf(1.34 MB)

MTC Case Series Registry Protocol February 2023_FINAL_Redacted.pdf(957.98 KB)

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 type:

Non-interventional study

Main study objective:

Systematically monitor the annual incidence of MTC through North American Association of Central Cancer Registries (NAACCR) to identify any possible increase related to the introduction of long-acting GLP-1 RAs. Establish a registry of incident cases of MTC in order to characterize their medical histories and possible risk factors, including history of treatment with long-acting GLP-1 RAs.

Study drug and medical condition

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

DULAGLUTIDE

EXENATIDE

LIRAGLUTIDE

SEMAGLUTIDE

Anatomical Therapeutic Chemical (ATC) code

(A10BJ05) dulaglutide

dulaglutide

(A10BJ01) exenatide

exenatide

(A10BJ02) liraglutide

liraglutide

(A10BJ06) semaglutide

semaglutide

Medical condition to be studied

Medullary thyroid cancer

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

6750

Study design details

Outcomes

A record of medullary thyroid carcinoma (MTC) identified from the US state/regional population-based cancer registries

---

Data analysis plan

Descriptive statistics will be used to characterize potential risk factors, including drug exposures, radiation exposure, lifestyle factors, environmental exposures, and other characteristics (including family history of MEN syndromes or FMTC history). Exposure to long-acting GLP-1 RAs will be characterized by dose and duration of exposure prior to the diagnosis of MTC.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Participating state cancer registries in the United States.

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

No