To examine the impact of additional confounder adjustment for the potential association between second line T2DM therapy and thyroid cancer: a nested case-control study (GLP1i and thyroid cancer)

First published: 08/09/2023

Last updated: 13/12/2023

Study Finalised

Administrative details

EU PAS number

EUPAS106600

Study ID

106601

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

A recent nested case-control analysis performed in the SNDS database (Bezin et al, 2023) showed an association with an increased risk of all thyroid cancer and medullary thyroid cancer with use of Glucagon-like peptide-1 agonists (GLP-1 RA) in people with T2DM, in particular after 1–3 years of cumulative treatment. However, it was not possible to adjust for certain potential confounders in the association with thyroid cancer that were not captured in that database, such as smoking status or body mass index. Our study aims to examine the potential impact of adjusting for missing confounders on the association with thyroid cancer in people with T2DM by attempting to reproduce the design of the French NCCS study.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

Study institution contact

Daniel Morales daniel.morales@ema.europa.eu

Study contact

daniel.morales@ema.europa.eu

Primary lead investigator

Daniel Morales

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 20/06/2023

Actual: 20/06/2023

Study start date

Planned: 01/08/2023

Actual: 01/08/2023

Data analysis start date

Planned: 15/08/2023

Actual: 15/08/2023

Date of final study report

Planned: 01/09/2023

Actual: 01/09/2023

Sources of funding

- EMA

Study protocol

GLP1RA i and risk of thyroid cancer protocol.pdf(937.01 KB)

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Other

If ‘other’, further details on the scope of the study

evaluation of counfounders impact

Main study objective:

To calculate crude and adjusted effect estimates for GLP1-agonists and the association with thyroid cancer based upon the design for confounding adjustment in the study by Bezin et al. study. To determine the impact of additional adjustment for smoking status, BMI, and history of alcohol use/abuse on the effect estimates for GLP1-agonists (+/- other seco

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A10BJ) Glucagon-like peptide-1 (GLP-1) analogues

Glucagon-like peptide-1 (GLP-1) analogues

Medical condition to be studied

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

64000

Study design details

Outcomes

Thyroid cancer

Data analysis plan

A cohort of diabetic patients will be created. From this, controls will be sampled through risk set sampling, matched for age, gender, cohort follow-up, and diabetes duration. The matching approach may be refined depending on the feasibility of identifying controls. Conditional logistic regression will be used to examine the association between each exposure and outcome. Odds ratios in this context can be considered akin to rate ratios.

Documents

Study results

Study results Final.pdf(1.32 MB)

Study publications

Bezin J, Gouverneur A, Pénichon M, Mathieu C, Garrel R, Hillaire-Buys D, Parien…

Data management

Data sources

Data source(s), other

IMRD United Kingdom

Data sources (types)

Electronic healthcare records (EHR)

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