NN9535-4447 Epidemiological assessment of the risk for pancreatic cancer associated with the use of semaglutide in patients with type 2 diabetes- A cohort study based on Nordic registry data

First published: 30/09/2020

Last updated: 23/04/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/49276

EU PAS number

EUPAS37258

Study ID

49276

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] Norway
- [ ] Sweden

Study description

The aim of this study is to evaluate whether exposure to semaglutide influences the risk of pancreatic cancer in patients with type 2 diabetes. This is achieved by estimating the risk of pancreatic cancer associated with semaglutide use as compared to use of other non-incretin antidiabetic drugs used at a similar stage as Ozempic® or Rybelsus® in the treatment of type 2 diabetes. A multi-national, non-interventional study based on health care data from Denmark, Sweden, and Norway is conducted covering the period 2018-2023. A cohort study design is used comparing new users of semaglutide with new users of other antidiabetic drugs used at a similar stage as Ozempic® or Rybelsus® in the treatment of type 2 diabetes (active comparators). Active comparators will include the following non-incretin antidiabetic agents: sulphonylureas, sodium-glucose co-transporter 2 inhibitors, and insulin subdivided into i) basal insulin only and ii) basal + bolus insulin or premix insulin. Propensity scores are used to match new users of semaglutide with new users of active comparators. National prescription-, cancer- and patient registries are used to identify exposure to antidiabetic agents, pancreatic cancer cases, and covariates to be used in propensity score matching. This study is a post-authorisation safety study (PASS).

Study status

Ongoing

Research institutions and networks

Institutions

University of Southern Denmark (SDU)

Denmark

First published: 01/02/2024

Last updated: 27/03/2024

Institution | Educational Institution

Centre for Pharmacoepidemiology, Karolinska Institutet (CPE-KI)

Sweden

First published: 24/03/2010

Last updated: 23/04/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

Pharmacoepi center, University of Southern Denmark

Denmark

First published: 22/04/2010

Last updated: 27/07/2023

Institution | Educational Institution | ENCePP partner

Department of Chronic Diseases, Pharmacoepidemiologic Research Group, Norwegian Institute of Public Health (NIPH)

Norway

First published: 29/04/2010

Last updated: 06/05/2024

Institution | Laboratory/Research/Testing facility | Other | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Anton Pottegård

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/11/2018

Actual: 01/11/2018

Study start date
Planned: 01/12/2020

Actual: 26/01/2021

Date of final study report
Planned: 31/03/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novo Nordisk A/S

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)

Other study registration identification numbers and links

UTN- U1111-1214-6228

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

To estimate the risk of pancreatic cancer associated with semaglutide use as compared to use of other non-incretin antidiabetic drugs used at a similar stage as Ozempic® or Rybelsus® in the treatment of type 2 diabetes.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

SEMAGLUTIDE

Medical condition to be studied

Type 2 diabetes mellitus

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

600000

Study design details

Outcomes

The endpoint used to address the primary objective is the occurrence of first time (i.e. incident) malignant neoplasm of pancreas as defined by relevant diagnostic codes.

Data analysis plan

The propensity for initiating treatment with semaglutide as opposed to active comparators is estimated using logistic regression to determine the association between covariates and semaglutide initiation. The propensity score is used to

match new users of semaglutide to new users of active comparators. Ozempic® and Rybelsus® initiation will be handled in two separate propensity score models. Further, patients who are treated/not treated with semaglutide as opposed to active comparators against prediction are removed by asymmetric trimming of the tails of the propensity score. In the final study sample, the hazard ratios with 95% confidence intervals for pancreatic cancer comparing users of semaglutide to users of active comparators is estimated by using a Cox proportional hazards model. Several supplementary analyses are planned as well as sensitivity analyses to check the influence from the analytical/design choices on the study findings.

Documents

Study report

First Progress Report NN9535-4447.pdf(224.86 KB)

Progress report NN9535-4447_3.pdf(293.98 KB)

_ Regulatory Progress Report NN9535-4447 progress report_2.pdf(221.29 KB)

Study, other information

_ Regulatory Progress Report NN9535-4447 progress report_2.pdf(221.29 KB)

Progress report NN9535-4447_3.pdf(293.98 KB)

Data management

ENCePP Seal

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

2020-0065 Declaration of Interests.pdf(903.89 KB)

Composition of steering group and observers

ENCePP Seal Composition of Steering Group and Observers.pdf(7.63 KB)

Data sources

Data source(s)

Danish registries (access/analysis)

Data source(s), other

Danish Registries (access/analysis)

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Other

Data sources (types), other

Exposure registry

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