Association between exposure to GLP-1 receptor agonists and risk of suicide-related and self-harm-related events

First published: 07/03/2024

Last updated: 15/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS1000000052

Study ID

1000000052

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Cohort study aimed at investigating the association between GLP-1 receptor agonists and increased risk of suicide-related and self-injury-related events.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Andrei Barbulescu

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 15/08/2023

Actual: 15/08/2023

Study start date
Planned: 15/09/2023

Actual: 15/09/2023

Data analysis start date
Planned: 27/09/2023

Actual: 27/09/2023

Date of final study report
Planned: 08/11/2023

Actual: 14/11/2023

Sources of funding

- EMA

Study protocol

FINAL_Protocol - Suicidal ideation and GLP1a_v1.6.pdf (1011.55 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Main study objective:

Is the use of GLP-1 receptor agonists associated with an increased risk of suicide-related and self-harm-related events when compared to patients who are prescribed SGLT-2 inhibitors among T2DM patients?

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

GLP-1 receptor agonists

Medical condition to be studied

Suicidal ideation

Self-injurious ideation

Suicide attempt

Completed suicide

Additional medical condition(s)

Self-injury/self-harm

Population studied

Short description of the study population

The population eligible for the study will consist of patients:
- registered with a GP-practice covered by IQVIA™ Medical research data (IMRD),
- who initiated treatment with GLP-1 receptor agonists or SGLT-2 inhibitors (new users) during the study period,
- who had not used GLP-1 receptor agonists or SGLT-2 inhibitors before index-date (i.e., date of index treatment initiation and the start of follow-up in the study),
- with at least one year (365 days) of recorded medical history prior to index-date,
- with at least one diagnosis of T2DM before index-date,
- with no history of suicide-related or self-harm-related events prior to index-date,
- who have been treated with biguanides (e.g., metformin, which is considered first-line antidiabetic treatment according to NICE guidelines (NICE, 2022))

before index-date.

No exclusion will be applied according to age.

Age groups

Documents

Study report

Final study report_Suicidal ideation and GLP1.pdf (4.35 MB)

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)

IQVIA Medical Research Data - OMOP

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes