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

First published: 07/03/2024
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Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/1000000052

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 institution 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

Name of medicine, 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
All

Documents

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

Data management

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