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

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 institutions and networks

Institutions

European Medicines Agency (EMA)

First published: 01/02/2024

Last updated: 01/02/2024

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