Prevalence and patterns of medication deintensification following severe hypoglycemia among older adults with diabetes

First published: 03/11/2020

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Study Ongoing

Administrative details

EU PAS number

EUPAS37902

Study ID

39911

DARWIN EU® study

No

Study countries

United States

Study description

This study will explore real-world deintensification practices of hypoglycemic medications following hypoglycemia-related ED visit or hospitalization in older adults with diabetes. Aim 1: We will examine the incidence of sulfonylurea and insulin deintensification following hypoglycemia-related ED visit or hospitalization and identify patient factors associated with deintensification. Aim 2: Explore patterns of diabetes regimen deprescribing and prescribing following hypoglycemia-related ED visit or hospitalization.

Study status

Ongoing

Research institutions and networks

Institutions

University of North Carolina at Chapel Hill

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Institution

Contact details

Study institution contact

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Primary lead investigator

Anastasia-Stefania Alexopoulos

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 07/08/2020

Actual: 07/08/2020

Study start date

Planned: 07/08/2020

Actual: 07/08/2020

Date of final study report

Planned: 30/04/2020

Sources of funding

- Other

More details on funding

NIH funding

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:

Disease epidemiology

Main study objective:

The main objective of this study is to understand insulin and sulfonylurea prescription practices after an episode of severe hypoglycemia.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Diabetes mellitus

Hypoglycaemia

Population studied

Age groups

- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Renal impaired

Hepatic impaired

Immunocompromised

Estimated number of subjects

350.000

Study design details

Outcomes

Deintensification of insulin and/or sulfonylurea therapy following hypoglycemia-related ED visit or hospitalization, Describing prescription patterns of glucose-lowering drugs before and after hypoglycemia-related ED visit or hospitalization event.

Data analysis plan

Aim 1 We will determine crude cumulative incidence of deintensification following hypoglycemia. Multivariate logistic regression modelling will be used to assess the relationship between patient factors and deintensification versus no deintensification following hypoglycemia. Successively complex models will be built to capture individual demographic and clinical factors, diabetes complications and comorbidities, medication use, and health-care utilization. Aim 2: We will estimate the probability of filling each glucose-lowering drug before and after hypoglycemia-related ED visit (i.e. index event). This will be done in a) the full sample, and b) by baseline diabetes regimen (e.g. basal/bolus, basal only, premixed, oral agents only). We will also use a latent class analysis approach to characterize latent groups of diabetes medication trajectories pre- and post-index event.

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 sources (types)

Administrative healthcare records (e.g., claims)

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