The impact of metformin and physical exercise interaction on HbA1c, lipid profile and functional capacity (Metformin and physical exercise interaction)

First published: 25/05/2016

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Study Ongoing

Administrative details

EU PAS number

EUPAS13582

Study ID

28824

DARWIN EU® study

No

Study countries

Canada

Study description

We aim to study the interaction between metformin use and physical exercise among diabetic patients, and examine the association between different doses of exercise on glycated haemoglobin (HbA1c) level, lipid profile and functional capacity. We will construct a cohort of diabetic and non-diabetic patients using the electronic records of the Cardiac Wellness Program in Moncton, New Brunswick. A retrospective cohort design will be used. Diabetic patients will be identified as having a recorded diagnosis of diabetes at admission. The primary outcomes will be the HbA1c level, the lipid profile and the peak functional capacity measured at discharge. Metformin use will be measured through recorded prescriptions and physical exercise will be defined as the total energy cost of exercise sessions conducted within the program period. Directed acyclic graphs (DAG) will be used to identify potential confounders. The classes of confounding variables that will be assessed include: 1) sociodemographic variables, 2) baseline comorbidities and 3) diabetes and exercise related variables. Multiple linear and logistic regression models will be used to estimate the effect of metformin use, exercise dosage, and their interaction.

Study status

Ongoing

Research institutions and networks

Institutions

Centre de formation médicale du Nouveau-Brunswick

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Institution

Contact details

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Primary lead investigator

Sherif Eltonsy

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/05/2016

Actual: 01/05/2016

Study start date

Planned: 20/06/2016

Actual: 08/07/2016

Data analysis start date

Planned: 31/03/2017

Date of interim report, if expected

Planned: 31/07/2017

Date of final study report
Planned: 31/12/2018

Sources of funding

- Other

More details on funding

Maritime SPOR SUPPORT Unit (MSSU)

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:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Effectiveness study (incl. comparative)

Other

If ‘other’, further details on the scope of the study

Treatments interaction

Main study objective:

To examine the impact of the interaction between metformin use and physical exercise on HbA1c level, lipid profile and functional capacity among diabetic adults. Also to examine the effect of different doses of exercise on the primary outcomes among diabetic metformin users.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

METFORMIN

Medical condition to be studied

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

800

Study design details

Outcomes

1) the HbA1c level 2) the lipid profile measured at discharge 3) the distance walked over a total of six minutes, using the standard 6-minute walk test (6MWT).

Data analysis plan

Directed acyclic graphs (DAG) will be used to identify potential confounders and specify variables to be included in the models. DAGs will be used to estimate both the total and direct effects of exercise doses in separate models.

Documents

Study publications

Eltonsy S, Dufour Doiron M, Simard P, Jose C, Senechal M, Bouchard DR, LeBlanc ...

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)

Electronic healthcare records (EHR)

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