Effect of Incretin Analogues and Dipeptidyl-peptidase-IV inhibitors on colorectal cancer risk

First published: 28/04/2015

Last updated: 27/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS9592

Study ID

13643

DARWIN EU® study

No

Study countries

☐ United States

Study description

This will be a retrospective cohort study using a new-user active comparator design on Medicare Part A, B and D claims data from 2007-2012. The study population consists of Medicare enrollees initiating incretin-based drugs (GLP-1ra or DPP-4i) or other antidiabetic drugs (TZDs, sulfonylureas or long-acting insulins). New users of incretin-based drugs and other antidiabetic drugs will be compared with respect to incidence of colorectal cancer (primary outcome) and incidence of colorectal cancer combined with benign colorectaltumors (secondary outcome) adjusted for baseline information collected prior to drug initiation.

Study status

Finalised

Research institutions and networks

Institutions

University of North Carolina at Chapel Hill

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Institution

Gillings School of Public Health

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Til Stürmer

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/04/2015

Actual: 01/04/2015

Study start date

Planned: 01/04/2015

Actual: 01/04/2015

Data analysis start date

Planned: 01/04/2015

Actual: 01/04/2015

Date of final study report

Planned: 29/04/2016

Actual: 10/05/2016

Sources of funding

- Other

More details on funding

Unfunded

Study protocol

Colorectal Cancer Protocol clean 28APR2015.pdf(258.61 KB)

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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

The primary objective of this study is to examine the effect of initiation of incretin-based therapies (DPP-4s and GLP-1s) relative to other anti-diabetic therapies (sulfonylureas, TZDs and long-acting insulins) on the incidence of colorectal cancer based on a new-user active comparator design.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A10AE) Insulins and analogues for injection, long-acting

Insulins and analogues for injection, long-acting

(A10BB) Sulfonylureas

Sulfonylureas

(A10BG) Thiazolidinediones

Thiazolidinediones

(A10BH) Dipeptidyl peptidase 4 (DPP-4) inhibitors

Dipeptidyl peptidase 4 (DPP-4) inhibitors

Medical condition to be studied

Diabetes mellitus

Population studied

Short description of the study population

66 years and older Medicare fee-for-service beneficiaries (20% random sample) who were enrolled in Medicare Part A, B, and D plans for at least one calendar month during 2007-2012 and initiating incretin-based drugs (GLP-1ra or DPP-4i) or other antidiabetic drugs (TZDs, sulfonylureas or long-acting insulins).

Age groups

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Diabetes mellitus patients

Estimated number of subjects

175000

Study design details

Outcomes

Incidence of colorectal cancer, Incidence of colorectal cancer or benign colorectal tumors, incidence of diagnostic work-up

Data analysis plan

New-users of incretin-based therapies will be compared with new users of sulfonylureas, TZDs or long-acting insulins with respect to incidence of colorectal cancer diagnosis and the incidence of colorectal cancer or benign colorectal tumors. Using propensity score weighting methods, Inverse Probability of Treatment Weighting (IPTW) and Standardized MorbidityRatio Weighting (SMRW), we will implement COX models overall and stratified by time since initiation. Balance of the covariates will be assessed in the weighted pseudo-population and within deciles of the propensity score. Inverse probability weighted Kaplan-Meyer survival functions will be compared between our cohorts, adjusted for the same baseline covariates. The main effect measure estimate will be standardized hazard ratios with the assumptionthat there is no unmeasured confounding. Please see full protocol for additional details and description of secondary and sensitivity analyses.

Documents

Study results

Htoo et al GLP1 and DPP4 and cancer incidence.pdf(525.13 KB)

Study publications

Htoo, P.T., Buse, J.B., Gokhale, M. et al. Effect of glucagon-like peptide-1 re...

Data management

Data sources

Data source(s), other

20% random sample of Medicare claims data from 2007-2012 United States

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