ASPIrin use and colorectal CANcer risk (ASPICAN)

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/24908

EU PAS number

EUPAS24907

Study ID

24908

DARWIN EU® study

No

Study countries

☐ Italy

Study description

Aspirin has been associated with a reduced risk of Colorectal cancer (CRC) and its use for the primary prevention of CRC has been debated for a long time. Recently, the United States Preventive Services Task Force recommended low-dose aspirin use for the primary prevention of cardiovascular diseases (CVD) and CRC among “adults aged 50 to 59 years who have a 10% or greater 10-year CVD risk ...". To date, different observational studies investigated this topic considering different patients populations and study designs to minimize the effect of possible residual and/or uncontrolled confounders with respect to the association between LDA use and CRC. To the best of our knowledge, no study have addressed this issue within a population of patients for which LDA use should be expected, i.e. in secondary cardiovascular prevention.Using regional administrative data from Tuscany, Italy (>3.5 million inhabithants), we will performe a case-control study nested in a cohort of patients with first occurrence of a CVD between 2005-2010 (cohort entry). The 5th anniversary after the index hospital discharge will be the start of the period at risk for the occurrence of CRC. Each patient will be followed until the occurrence of the study outcome or any other censoring event (death, exit from the database, other cancer types, 31 December 2016) whichever came first. The date of occurrence of CRC will be the case index date. Per each case, up to 5 controls matched by sex, age and year of cohort entry. According to utilization of low-dose aspirin (LDA) prior to index date, we will define “ever use” as 2 or more LDA dispensings and “nonuse” as fewer than 2 dispensings. We will than model the exposure within the ever use category according to recency, continuity, duration, prescribed daily dose and average daily amount of LDA received during follow-up. Multivariable logistic regression will be used to estimate Odds Ratio and 95% IC intervals for the association between CRC and LDA.

Study status

Ongoing

Research institutions and networks

Institutions

Agenzia regionale di sanità della Toscana (ARS)

Italy

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Institution **EU Institution/Body/Agency** **ENCePP partner**

ISPRO Florence, Italy

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Leonardo Ventura

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 09/01/2017

Study start date
Actual: 10/07/2017

Date of final study report
Planned: 04/03/2019

Sources of funding

- Other

More details on funding

ARS and ISPRO

Study protocol

ASPICAN_ENCEPP Protocol_v1.pdf(111.53 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:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The aim of this study is to investigate the association between LDA use and the risk of developing CRC in patients in secondary cardiovascular prevention.

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

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

ACETYLSALICYLIC ACID

Medical condition to be studied

Colorectal cancer

Population studied

Short description of the study population

Patients with a first hospitalization for cardiovascular disease (CVD) during the period 2005-2010.

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)

Special population of interest

Other

Special population of interest, other

Colorectal cancer patients

Estimated number of subjects

35000

Study design details

Outcomes

New onset of colorectal cancer

Data analysis plan

Use of LDA in the study cohort will be described during the first 5 years from cohort entry according to the exposure categories defined above. Characteristics of the full study cohort will be described at cohort entry and at start of at risk period.The incidence rate of CRC will be calculated using the

number of observed cases as the numerator and the total amount of person-time cumulated during the “period at risk” (i.e. after the fifth year from cohort entry) as the denominator, stratified by sex and age group. Multivariable conditional regression will applied to estimate odds ratio and 95% confidence intervals for the association between LDA use and CRC.

Data management

Data sources

Data source(s)

ARS Toscana

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

Unknown