Riesgo de cáncer colorrectal asociado al uso de medicamentos: estudio de casos y controles (IJG-CCR-2015)

First published: 08/03/2016

Last updated: 08/03/2016

Study Ongoing

Administrative details

EU PAS number

EUPAS12697

Study ID

12698

DARWIN EU® study

No

Study countries

Spain

Study description

Colorectal cancer (CRC) is a heterogeneous disease. It has been reported that some chronic exposure to drugs can modulate the risk of CRC, and it has been studied possible preventive measures to detect if some exposures may increase the risk of CRC. Most current information comes from studies in Anglo-Saxon or northern European countries. Our population characteristics (lower cardiovascular risk and different diet) may determine baseline differences in risk. It is important to see if there are changes CRC risk associated with drugs already described in other populations, whose dietary characteristics are also observed and cardiovascular risk are different. It is therefore proposed to study CRC risk associated with drug exposures described as protective or risk factors. In addition, the retrospective study of chronic exposure to a broad spectrum of drugs in an affected population of CRC could allow associations identification previously undescribed. These associations could be evaluated in detail in order to generate new hypotheses. This case-control study assesses the association between CRC and chronic exposure to drugs.It will be obtain data from the Information System for the Improvement of Research in Primary Care (clinical variables, laboratory and prescribed medication) in 2010-2015, including more than 5,000 cases with the diagnosis of CRC and its controls. We will analyze CRC risk associated with chronic exposure to drugs adjusted by risk factors by logistic regression. We will analyze dose-response drugs associations showing statistical significance, in terms of duration of exposure and cumulative dose relationship. Possible drug interactions and potential effect modifiers exhibitions will be explored.

Study status

Ongoing

Research institutions and networks

Institutions

Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

Spain

First published: 05/10/2012

Last updated: 09/07/2026

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

Contact details

Study institution contact

Maria Angeles Quijada Manuitt aquijada@idiapjgol.org

Study contact

aquijada@idiapjgol.org

Primary lead investigator

Maria Angeles Quijada Manuitt

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/09/2015

Actual: 27/11/2015

Study start date
Planned: 02/02/2015

Actual: 01/03/2016

Data analysis start date
Planned: 01/04/2016

Date of final study report
Planned: 01/11/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bioiberica

Study protocol

Protocolo CCR v04 08-03.pdf (651.59 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Main study objective:

To assess the association between CRC and chronic exposure to different pharmacological groups and active principles

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Medical condition to be studied

Colorectal cancer

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

30.000

Study design details

Outcomes

demographic and anthropometric characteristics (age, sex, geographic distribution, MEDEA index, physical activity and BMI), toxic habits (smoking, alcohol), medical history (diabetes mellitus, inflammatory bowel disease, polyps of the colon and rectum, adenomatous colon polyps, intestinal malabsorption, cardiovascular disease, cerebrovascular or peripheral vascular disease, etc.), Charlson index, frequenting primary care (number of visits in the last year) and the number of prescriptions (active on index date), laboratory parameters (hemoglobin, hematocrit, leukocytes, liver and lipid profile, glycemia and glycated hemoglobin, glomerular filtration rate last predetermination to the index date), and drug exposure

---

Data analysis plan

We will analyze CRC risk associated with chronic exposure to drugs adjusted by risk factors (age, sex, and other variables that are shown associated with the disease and possibly the exhibitions of the population) by logistic regression. We will analyze dose-response drugs associations showing statistical significance, in terms of duration of exposure and cumulative dose relationship. Possible drug interactions and potential effect modifiers exhibitions will be explored.Associations will be expressed as odds ratio estimates and confidence intervals of 95%.

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 source(s)

The Information System for Research in Primary Care (SIDIAP)

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