# 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.

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**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

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

## Contact details

**Study institution contact**

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Study contact

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**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

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**Study start date**
Planned: 02/02/2015

Actual: 01/03/2016

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**Data analysis start date**
Planned: 01/04/2016

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**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:**

Non-interventional study

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**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**

30000

# 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