

Evaluation of colon cancer screening on colon cancer mortality

Submission date 01/02/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/02/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/11/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The impact of colorectal cancer population screening strategies on mortality outside of randomized controlled trials remains unknown. The objective of this study was to measure the mid-term impact of the introduction of colorectal cancer screening programmes on colorectal cancer mortality rates across Spain.

Who can participate?

The entire population of Spain

What does the study involve?

The research team review the number of deaths by colon cancer by reviewing Spanish Statistical Office data of mortality recorded in a database every 6 months for the 17-year study period. Information about the screening implementation and uptake is also observed using from regional registries.

What are the possible benefits and risks of participating?

There are no direct benefits or risks involved with participating

Where is the study run from?

Hospital Clínic de Barcelona (Spain)

When is the study starting and how long is it expected to run for?

January 2019 to February 2019.

Who is funding the study?

Investigator-initiated and funded.

Who is the main contact?

Miquel Serra-Burriel
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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HCB/2018/0109

Study information

Scientific Title

Impact of population screening on colorectal cancer mortality: a natural experiment

Study objectives

1. Has the implementation of colorectal cancer screening in Spanish provinces that adopted it been effective in reducing colorectal cancer mortality?
2. Has the implementation of colorectal cancer screening in Spanish provinces had a differential effect by gender?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 19/02/2019 Ethics Committee, Hospital Clínic de Barcelona (Villarroel, 170, 08036 Barcelona, Spain; +34 93 227 57 66; ceic@clinic.cat), ref HCB/2018/0109.

Study design

Observational natural experiment

Primary study design

Observational

Secondary study design

Natural Experiment

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

No participant information sheet available.

Health condition(s) or problem(s) studied

Colorectal cancer

Interventions

The present study is an ecological analysis of colorectal cancer-specific deaths at a province level. We compare age-standardised mortality rates in provinces that were exposed to screening with provinces that did not.

The individual's data comes from the Spanish Statistical Office, and only includes death certificate data combined with population census data at a province level. The data was obtained through the INE

[https://www.ine.es/dyngs/INEbase/es/operacion.htm?](https://www.ine.es/dyngs/INEbase/es/operacion.htm?c=Estadistica_C&cid=1254736176780&menu=resultados&secc=1254736195294&idp=1254735573)

[c=Estadistica_C&cid=1254736176780&menu=resultados&secc=1254736195294&idp=1254735573](https://www.ine.es/dyngs/INEbase/es/operacion.htm?c=Estadistica_C&cid=1254736176780&menu=resultados&secc=1254736195294&idp=1254735573)

Intervention Type

Other

Primary outcome measure

Current primary outcome measure as of 25/02/2019:

Mortality rates will be measured using the biannual CRC-specific 1999 age-standardised mortality rates (measured by the National Statistical Office of Spain) for the population aged 50-69 years old.

Previous primary outcome measure:

Mortality rates will be measured using the biannual CRC-specific 1999 age-standardised mortality rates (measured by the National Statistical Office of Spain) for the population aged 50-79 years old.

Secondary outcome measures

1. Biannual CRC-specific 1999 Age-standardised mortality rates for overall population, measured by the National Statistical Office of Spain (INE)
2. Biannual CRC-specific 1999 Age-standardised mortality rates for population aged between 40 to 49 years old, measured by the National Statistical Office of Spain (INE)
3. Biannual CRC-specific 1999 Age-standardised mortality rates for population aged between 0 to 39 years old, measured by the National Statistical Office of Spain (INE)

Overall study start date

02/01/2019

Completion date

28/02/2019

Eligibility

Key inclusion criteria

The entire population of Spain

Participant type(s)

All

Age group

All

Sex

Both

Target number of participants

The entire population of Spain: 46000000

Key exclusion criteria

Resident of Spanish provinces that started screening after 2009.

Date of first enrolment

10/01/2019

Date of final enrolment

30/01/2019

Locations

Countries of recruitment

Spain

Study participating centre

Hospital Clínic de Barcelona

Villarroel, 170

Bacelona

Spain

08036

Sponsor information

Organisation

Pompeu Fabra University

Sponsor details

C/ Ramón Trias-Fargas 25-27

Barcelona

Spain

08005

Sponsor type

University/education

Website

<https://www.upf.edu/>

ROR

<https://ror.org/04n0g0b29>

Funder(s)**Funder type**

Other

Funder Name

Investigator initiated and funded

Results and Publications**Publication and dissemination plan**

Planned publication of findings as an academic paper in a high-ranking, open access medical journal. After publication, a press release will be created that is accessible to all with assistance from the Pompeu Fabra University external communications team. Results will also be presented at national and international public health conferences.

Intention to publish date

01/04/2019

Individual participant data (IPD) sharing plan

Due to compliance with the Spanish Statistical Office regulation, data will not be available at the end of the study, but can be accessed through: <https://www.ine.es/welcome.shtml>.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/03/2021	26/11/2020	Yes	No