Commonly prescribed drugs and association with breast, colorectal and lung cancer progression: a nested case-control study

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Study Planned

Administrative details

EU PAS number

EUPAS1863

Study ID

27410

DARWIN EU® study

No

Study countries

United Kingdom

Study description

There is growing evidence that commonly prescribed cardiovascular medications such as betablockers, angiotensin converting enzyme inhibitors and angiotensin II type I receptor blockers, pain relief medications such as nonsteroidal antiinflammatory drugs and aspirin and bisphosphonates (drugs that prevent loss of bone mass), may have unintended positive consequences in relation to the prevention of cancer metastasis and recurrence. To date however, there have been very few epidemiological studies which have investigated this association. Since 2008 in Northern Ireland (NI), prescriptions given to any patient registered with a GP have incorporated a 2D barcode. Each barcode stores information pertaining to the patient, practice and medication to which the prescription pertains. When prescriptions are dispensed at community pharmacies the scripts are sent to the Business Services Organisation (BSO) were the 2D barcode is scanned and the information entered into an Enhanced Prescribing Database (EPD). EPD is therefore a central database of prescribed and dispensed medications for approximately 1.9 million patients registered with a GP in NI. The Northern Ireland Cancer Registry (NICR) was established in 1994 and uses an automated computer system, fed with patient data from hospital and histopathology records and death notifications from a variety of sources, to collate information on new diagnoses of cancer in the province.This study will link tumour staging and treatment data collated from the NICR on patients diagnosed with primary breast, colorectal and lung cancer between 1st July 2008 and 31st Dec 2011 (inclusive) to commonly prescribed medications held on these patients in the BSO; each patient's individual Health & Care number will be used to link the records in each dataset. This study will help identify the class and dose of drug(s) most likely to influence cancer progression and recurrence and assess their effects on cancer specific mortality.

Study status

Planned

Research institutions and networks

Institutions

Queen's University Belfast

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Institution | Educational Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Chris Cardwell

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/09/2011

Actual: 03/10/2011

Study start date

Planned: 31/10/2011

Data analysis start date
Planned: 01/01/2013

Date of interim report, if expected
Planned: 31/07/2012

Date of final study report
Planned: 20/12/2020

Sources of funding

- Other

More details on funding

Queen's University Belfast

Study protocol

Commonly prescribed drugs and association with cancer progression_protocol.pdf (760.39 KB)

NICR_EPD_Protocol_v1.2.pdf (707.35 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 type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Main study objective:

The principal study objective is to investigate the association between commonly prescribed cardiovascular, analgesic and bisphosphonate medications in relation to cancer specific and all cause mortality i.e.: assessment of the odds of dying from cancer or all causes between breast, lung and colorectal cancer patients taking vs. those not taking a variety of commonly prescribed medications.

Study Design

Non-interventional study design

Cohort

Case-control

Study drug and medical condition

Medical condition to be studied

Breast cancer female

Lung carcinoma cell type unspecified stage I

Lung carcinoma cell type unspecified stage II

Lung carcinoma cell type unspecified stage III

Lung carcinoma cell type unspecified stage IV

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

8398

Study design details

Outcomes

Primary outcomes of the study will be cancer specific and all cause mortality in relation to regular (>= 3 times/week for one month or more) use of NSAIDs and aspirin (including low dose aspirin (75mg)), angiotensin converting enzyme Inhibitors (ACE inhibitors), angiotensin receptor blockers (ARBs), β-blockers and bisphosphonates post-diagnosis of any stage breast, colorectal and lung cancer. A secondary outcome for this study will be to assess the odds of cancer recurrence (i.e.: a secondary occurence of the primary cancer after a period of remission) between patients using commonly prescribed medications and nonusers.

Data analysis plan

The statistical analysis for all three cancer cohorts (breast, colorectal and lung) will be handled using a time matched nested case-control analysis approach. Cohort members will be defined as a case if they have died from one of the three cancer sites or if they have developed a recurrence of their cancer. Up to 5 controls will be selected (matched on age in 5year intervals and gender) to cohort members (controls) who are still alive/have not developed disease recurrence at the time of the case’s death/cancer recurrence. Conditional logistic regression analysis will be used to calculate the odds of death and 95% confidence limits between those ever exposed vs. those never exposed to each of the intended drugs under study. Analysis will be stratified on age, menopausal status (in breast cancer analysis), gender and cancer site (in colorectal and lung cancer cohorts) and stage (all cancers). Additional analyses will be undertaken to the quantity and duration of drug use.

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 sources (types)

Disease registry

Drug dispensing/prescription data

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