

Aspirin use and prostate cancer mortality in men with high grade prostate cancer

First published: 08/02/2013

Last updated: 30/09/2013

Study

Finalised

Administrative details

EU PAS number

EUPAS3444

Study ID

4877

DARWIN EU® study

No

Study countries

Ireland

Study description

Observational studies have for many years reported associations between aspirin exposure and reduced incidence of many cancers including prostate cancer. More recently evidence has been building of an association between

aspirin use and reduced mortality in both meta-analyses and observational studies. The biological mechanisms proposed are the anti-platelet activity of aspirin, which may impede the spread of metastases, and also through the inhibition of the cyclooxygenase 2 (COX-2) enzyme, expressed in response to tumour growth factors and inflammation. Studies have reported COX-2 to be expressed at higher levels in higher grade tumours, which are associated with poorer outcomes. In prostate cancer the associations between aspirin use and reduced mortality have been strongest in men with localised disease. This study aims to examine the associations between aspirin use and mortality in men diagnosed with high grade prostate tumours. The analysis will be stratified by tumour stage, to assess whether the association between aspirin use and prostate cancer mortality is modified according to whether the disease is localised or advanced.

Study status

Finalised

Research institutions and networks

Institutions

Trinity College Dublin

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Kathleen Bennett

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/10/2010

Study start date

Actual: 01/10/2011

Data analysis start date

Planned: 01/02/2013

Date of final study report

Planned: 30/09/2013

Actual: 30/09/2013

Sources of funding

- Non-for-profit organisation (e.g. charity)

More details on funding

Irish Cancer Society

Study protocol

[ENCEPP Study Protocol Aspirin High Grade Prostate Cancer 30.01.2013.pdf](#)
(360.82 KB)

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Other

If 'other', further details on the scope of the study

Assessment of chemoprevention

Data collection methods:

Secondary use of data

Main study objective:

This study aims to examine the associations between aspirin use and prostate cancer mortality in men diagnosed with high grade prostate tumours.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

ACETYLSALICYLIC ACID

Medical condition to be studied

Neoplasm prostate

Population studied

Short description of the study population

Men aged 50-80 years at the time of prostate cancer diagnosis (ICD-O, C61), diagnosed as having a tumour with Gleason Score histology > 7 between 1st January 2001 and 31st December 2006

Age groups

- 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

Patients with high grade prostate tumours

Estimated number of subjects

1000

Study design details

Outcomes

Prostate cancer death

Data analysis plan

Linked National Cancer Registry of Ireland data (2001-2006) and prescription claims data from the Republic of Ireland will be used to carry out this study (NCRI-PCRS database). This study is restricted to men aged between 50 and 80 years at diagnosis with prostate cancer of Gleason Score > 7. Men diagnosed with prostate cancer at death/autopsy, or men with another invasive cancer,

excluding non-melanoma skin cancer, prior to their prostate cancer diagnosis will be excluded. Cox proportional hazards models with 95% Confidence intervals will be used to estimate Hazard Ratios (HR) for the association between aspirin use in the year prior to diagnosis and prostate cancer specific mortality. Stratification by tumour stage will determine a multiplicative interaction of the association between aspirin exposure and prostate cancer in localised compared to advanced tumours using ratio of HR (rHR).

Documents

Study results

[ENCEPP Study Report EF KB.pdf](#) (454.45 KB)

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.

Composition of steering group and observers

[ENCEPP Study Steering Group Aspirin High Grade Prostate Cancer 30.01.2013.pdf](#) (175.04 KB)

Data sources

Data source(s), other

NCRI-PCRS Database, Ireland

Data sources (types)

[Disease registry](#)

[Drug dispensing/prescription data](#)

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