Exposure to beta-blockers and survival in breast cancer patients: A cohort study using the UK General Practice Research Database.

First published: 25/04/2012

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Study Ongoing

Administrative details

EU PAS number

EUPAS2572

Study ID

2573

DARWIN EU® study

No

Study countries

United Kingdom

Study description

New therapeutic strategies are needed to reduce mortality in breast cancer patients. Recently, it has been proposed that cancer progression may be prevented by medicines in current use including beta-blockers (used to treat hypertension). We previously demonstrated that beta-blockers inhibit migration in breast and prostate cancer cells and in an observational study showed marked reductions in cancer-associated mortality and metastasis in breast cancer patients using beta-blockers. This study will be the largest yet to investigate beta-blockers and cancer progression in breast cancer patients. GPRD data allow detailed analysis of the timing of drug exposure and the effect on various outcome measures including mortality, cancer-specific mortality and cancer recurrence. Importantly, an analysis will use robust cancer data from UK cancer registries and robust death data (from the Office of National Statistics).

Study status

Ongoing

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

Powe Des

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/12/2011

Study start date
Actual: 01/03/2012

Date of final study report
Planned: 28/02/2013

Sources of funding

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

More details on funding

Cancer Research UK

Study protocol

Protocol beta blocker for ENCEPP_final.pdf (235.7 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:

Disease epidemiology

Main study objective:

The primary objectives of the proposed research are to examine whether female breast cancer patients who are exposed to beta-blockers have reduced cancer-specific mortality rates, all-cause mortality rates and recurrence rates.

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Medical condition to be studied

Breast cancer female

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

46.000

Study design details

Outcomes

Breast-cancer specific death, All cause mortalityBreast cancer recurrence

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Data analysis plan

In the primary analysis the main exposure will be beta-blocker usage determined from GP prescribing data. The main analysis will be conducted on

beta-blocker prescriptions in the period following diagnosis of cancer excluding the year prior to cancer death (or censoring). Packages and tablets of prescriptions for beta-blockers will be converted to daily defined doses (DDDs). Separate analyses will be conducted by type of beta-blockers based upon cardioselectivity and ISA activity (categorisations of beta-blockers shown in Appendix 1). A secondary analysis will be conducted on beta-blocker prescriptions in the period prior to cancer diagnosis (in patients registered for at least one year at their GP practice, to ensure prescriptions are recorded).

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)

Clinical Practice Research Datalink

Data sources (types)

Disease registry

Electronic healthcare records (EHR)

Other

Data sources (types), other

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