Translating basic science into improved patient outcomes in ovarian cancer: an Ireland-UK collaboration investigating common pharmacological exposures and tumour characteristics, recurrence, survival and mortality (Effects of Pharmacological exp. on Ovarian Cancer)

First published: 07/08/2014

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Study Ongoing

Administrative details

EU PAS number

EUPAS7211

Study ID

7212

DARWIN EU® study

No

Study countries

Ireland

United Kingdom

Study description

Almost 250,000 ovarian cancers are diagnosed worldwide each year. Incidence rates are high in northern Europe, including in Ireland and the UK. These countries have among the highest ovarian cancer mortality rates in the world. The relatively young average age and advanced stage at diagnosis, mean that ovarian cancer is a major burden. Lab-based research suggests that various commonly-used drugs (statins, beta-blockers and NSAIDs) might have potent anti-tumour effects in ovarian cancer. We will combine estimates from cancer registry linked, pharmacoepidemiology databases from Ireland (NCRI/PCRS), Northern Ireland (NICR/EPD) and Great Britain (CPRD/NCDR), to investigate associations between exposure to these three drug groups and ovarian cancer presentation, progression and outcomes. There are three outcomes of interest: (A) associations between pre-diagnosis drug exposure and stage at diagnosis, (B) associations between exposure to drugs and disease recurrence and (C) associations between exposure to drugs and cancer related mortality. Analysis of stage will use a nested case-control design and be performed using conditional logistic regression. Analyses of other outcomes will use a retrospective cohort design to investigate associations between pre- and post-diagnosis exposure. Cox proportional hazards models, with adjustment for known confounders will be used and the lagged time-varying covariate approach will be used to evaluate post-diagnosis exposure. Cohort estimates will be combined in a prospective meta-analysis.

Study status

Ongoing

Research institutions and networks

Institutions

National Cancer Registry Ireland

First published: 01/02/2024

Last updated: 01/02/2024

Institution

EMeRGe research group, Royal College of Surgeons in Ireland (RCSI EMeRGe group)

Ireland

First published: 02/03/2010

Last updated: 02/05/2023

Institution | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

Queen's University Belfast

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution

Queen's University Belfast Belfast, Northern Ireland (UK)

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Sharp Linda

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/05/2013

Actual: 01/05/2013

Study start date

Planned: 01/10/2013

Actual: 01/10/2013

Data analysis start date

Planned: 01/10/2014

Date of final study report
Planned: 31/12/2015

Sources of funding

- Other

More details on funding

Health Research Board, Ireland

Study protocol

Sharp et al. EPOC (ovarain) ENCePP protocol 20140807.pdf (731.9 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 principal study objective is to investigate the association between commonly prescribed medications and cancer-specific survival in the ovarian population.

Study Design

Non-interventional study design

Cohort

Case-control

Study drug and medical condition

Medical condition to be studied

Ovarian 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

2960

Study design details

Outcomes

The primary outcome of the study will be cancer specific mortality. It will be evaluated for association with use of statins, β-blockers, NSAIDs pre-diagnosis to ovarian cancer. Secondary outcomes for this study will be to assess the medication effects on all-cause mortality, cancer recurrence and the odds of distant disease at the time of diagnosis.

Data analysis plan

The statistical analysis for all three population cohorts (Ireland, Northern Ireland, United Kingdom) will performed separately and estimates combined using a prospective meta-analysis approach. The analysis will compare exposed versus unexposed, with exposure defined at the time of diagnosis (i.e. pre-diagnosis exposure). In each cohort, stage at diagnosis cases (Stage N1 or M1) will be compared to controls (matched on age, year of diagnosis) using conditional logistic regression to estimate odds ratios (OR) and 95% confidence intervals for exposure to each drug class. Cox proportional hazards models will be used to compute unadjusted and adjusted hazard ratios for other outcomes. Secondary analysis will consider exposure (including post-diagnostic period) as a time-varying dichotomous (ever/never) covariate. Exposure will be lagged by 6 months.

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

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