Studying drug exposure when disease is measured through accurate identification of an incident case: application to breast cancer in pregnancy (ConcePTION breast cancer demo)

First published: 04/10/2021

Last updated: 02/07/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/43394

EU PAS number

EUPAS43393

Study ID

43394

DARWIN EU® study

No

Study countries

- [ ] Finland
- [ ] Norway
- [ ] Spain
- [ ] United Kingdom

Study description

The objective is to evaluate which pharmaco-epidemiological methods are best suited to assess treatment modalities, including drug utilisation in pregnancy for malignant disease. The goal is to study drug exposure when disease is measured through accurate identification of an incident case. Therapies for pregnancy associated breast cancer (PABC) are used as motivating examples. We will particularly focus on improving methods for developing measurements of medication exposure in hospital settings / secondary and tertiary care. This drug utilisation study will describe patterns of medication use in PABC and in breast cancer in non-pregnant women (non-PABC). We will also assess whether time at breast cancer diagnosis and timing of medication use in pregnancy impacts maternal survival and pregnancy outcomes.

Study status

Ongoing

Research institutions and networks

Institutions

Finnish Institute for Health and Welfare (THL)

- [ ] Finland

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution | Laboratory/Research/Testing facility

Pharmacoepidemiology and Drug Safety Research Group (PharmaSafe), University of Oslo

Norway

First published: 19/10/2016

Last updated: 08/11/2016

Institution | Educational Institution | ENCePP partner

Drugs and Pregnancy, Finnish Institute for Health and Welfare (THL)

Finland

First published: 17/03/2010

Last updated: 20/03/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | ENCePP partner

The Foundation for the Promotion of Health and Biomedical Research of Valencia Region (FISABIO)

Spain

First published: 01/02/2024

Last updated: 05/11/2024

Institution

The Foundation for the Promotion of Health and Biomedical Research of Valencian Region, FISABIO Spain, University of Swansea Wales

Networks

ConcepTION

First published: 01/02/2024

Last updated: 01/02/2024

Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Maarit Leinonen

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 01/04/2019

Study start date
Actual: 08/05/2021

Date of final study report
Planned: 31/12/2024

Sources of funding

- EU institutional research programme

More details on funding

Innovative Medicines Initiative

Study protocol

Breast Cancer Protocol_PABC_Final_093021.pdf(935.55 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

Effectiveness study (incl. comparative)

Main study objective:

Our aim is to improve methods for developing measurements of medication exposure in hospital settings. This drug utilisation study will describe patterns of medication use in pregnancy associated breast cancer (PABC) and in breast

cancer in non-pregnant women. We will also assess whether time at diagnosis and timing of medication use in pregnancy impacts maternal survival and pregnancy outcomes.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L01D) CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

(L02) ENDOCRINE THERAPY

ENDOCRINE THERAPY

Medical condition to be studied

Breast cancer female

Breast cancer stage I

Breast cancer stage II

Breast cancer stage III

Breast cancer stage IV

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

2965

Study design details

Outcomes

Maternal overall and 5-year relative survival in woman with PABC vs non-PABC patients. Mode of delivery and the following pregnancy outcomes (termination of pregnancy, live birth, stillbirth, preterm birth, small for gestational age SGA) in women with PABC and non-PABC.

Data analysis plan

Descriptive analysis of cancer therapies used to treat breast cancer over the course of a pregnancy (prior to, during, after pregnancy) and during pregnancy (1st, 2nd or 3rd trimester) will be provided. 5-year relative survival analyses will be carried out using e.g. Cox proportional hazard regression and flexible parametric models to elucidate the complex associations between time-since-conception, medication exposure, breast cancer incidence and survival and to control for important confounders. Effects will be presented as relative risk estimates with CI describing the precision of the estimate (95% CI).

Data management

Data sources

Data source(s)

German Pharmacoepidemiological Research Database

SAIL Databank

Data source(s), other

Linkage of several registries Finland, Linkage of several registries Spain, Linkage of several registries United Kingdom

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Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Drug dispensing/prescription data

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prospective patient-based data collection

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