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

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# Administrative details

### **PURI**

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

### **EU PAS number**

EUPAS43393

### **Study ID**

43394

### **DARWIN EU® study**

Nο

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

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Institution Educational Institution Laboratory/Research/Testing facility

Pharmacoepidemiology and Drug Safety Research Group (PharmaSafe), University of Oslo
Norway
First published: 19/10/2016
<b>Last updated:</b> 08/11/2016
Institution

# 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

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

### **Networks**

# ConcepTION

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Network

### Contact details

**Study institution contact** 

### Maarit Leinonen

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

# 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

### **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