

# 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
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### 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.

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### 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

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**Study start date**

Actual: 08/05/2021

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**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

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### **Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Methodological aspects

### Study type

#### Study type list

##### **Study type:**

Non-interventional study

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##### **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

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### **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)

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## **Special population of interest**

Pregnant women

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## **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.

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## **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

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**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](#)

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**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

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No