

# CAnker Risk and INsulin analoGues (CARING) project

**First published:** 10/12/2013

**Last updated:** 23/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS5383

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### Study ID

11823

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### DARWIN EU® study

No

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### Study countries

- ☐ Denmark
  - ☐ Finland
  - ☐ Netherlands
  - ☐ Norway
  - ☐ Sweden
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## Study description

The CARING (CAncer Risk and INSulin analogues) project will obtain precise data on the incidence of cancer in diabetic patients and determine any link with use of various insulin and insulin analogues. The study will utilise high quality prescription databases and other national data sources, integrated at European level with advanced methods of harmonising data. The study will take into account potential confounders. The project aims to determine the influence of drug dose on risk, and through a risk model, identify predictors of cancer for insulin users. A review of published evidence combined with a study of tumour characteristics and gene expression in breast cancer tumour collections will aid understanding of potential mechanisms of cancer initiation and/or promotion by insulin.

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## Study status

Finalised

# Research institutions and networks

## Institutions

Division of Pharmacoepidemiology & Clinical Pharmacology (PECP), Utrecht Institute for Pharmaceutical Sciences (UIPS), Utrecht University

☐ Netherlands

**First published:** 01/03/2010

**Last updated:** 23/05/2024

**Institution**

**Educational Institution**

**ENCePP partner**

## Tampere University Hospital

☐ Finland

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

Educational Institution

Hospital/Clinic/Other health care facility

## Centre for Pharmacoepidemiology, Karolinska Institutet (CPE-KI)

☐ Sweden

**First published:** 24/03/2010

**Last updated:** 23/04/2024

**Institution**

Educational Institution

Laboratory/Research/Testing facility

Not-for-profit

ENCePP partner

## Department of Chronic Diseases, Pharmacoepidemiologic Research Group, Norwegian Institute of Public Health (NIPH)

☐ Norway

**First published:** 29/04/2010

**Last updated:** 06/05/2024

Institution

Laboratory/Research/Testing facility

Other

ENCePP partner

## Aarhus University Hospital

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

## Helsinki University Hospital (HYKS)

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

Aarhus University Hospital Aarhus, Denmark,  
University of Tampere Tampere, Finland,  
University of Helsinki Helsinki, Finland,  
Netherlands Cancer Institute Amsterdam,  
Netherlands

Networks

## CAncer Risk and INsulin analogues (CARING)

- ☐ Denmark
- ☐ Finland
- ☐ Netherlands
- ☐ Norway
- ☐ Sweden

**First published:** 13/12/2013

**Last updated:** 13/03/2024

Network

ENCePP partner

## Contact details

### Study institution contact

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Study contact

[m.l.debruin@uu.nl](mailto:m.l.debruin@uu.nl)

### Primary lead investigator

Marie L De Bruin

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 18/07/2011

Actual: 18/07/2011

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### **Study start date**

Planned: 01/11/2011

Actual: 01/11/2011

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### **Data analysis start date**

Planned: 01/08/2014

Actual: 01/08/2014

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### **Date of final study report**

Planned: 21/12/2015

Actual: 21/12/2015

## Sources of funding

- EU institutional research programme

## More details on funding

FP7 HEALTH.2011.4.2-2

## Study protocol

[CARING Common Protocol 3.0.pdf](#)(675.88 KB)

[CARING Common Protocol 3.3.pdf](#)(671.39 KB)

## 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:**

Assessment of risk minimisation measure implementation or effectiveness

#### **Main study objective:**

The primary aim of the study is to quantify the risk of cancer associated with the (long-term) use of insulin and insulin analogues by studying the effects of dosage, duration and/or intensity of insulin treatment on the likelihood of developing cancer and different types of cancer.

## Study Design

### **Non-interventional study design**

Cohort

## Study drug and medical condition

## Anatomical Therapeutic Chemical (ATC) code

(A10A) INSULINS AND ANALOGUES

INSULINS AND ANALOGUES

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## Medical condition to be studied

Prostate cancer

Breast cancer

Colorectal cancer

Non-small cell lung cancer

Bladder cancer

Skin cancer

Cervix carcinoma

Non-Hodgkin's lymphoma

Pancreatic carcinoma

Hepatobiliary 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)

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### Estimated number of subjects

5000000

## Study design details



## Outcomes

- prostate cancer - breast cancer - colorectal cancer - lung cancer - bladder cancer - melanoma of skin - cancer of corpus uteri - non-Hodgkin lymphoma - pancreatic cancer - liver cancer, Any cancer, excluding non-melanoma skin cancer.

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## Data analysis plan

We will perform a series of population-based cohort studies, using the Norwegian, Swedish, Danish and Finnish National Health Registries and the Clinical Practice Research Datalink (CPRD) from the United Kingdom. Studies will be performed in all databases separately, and multi-country data will be combined using several approaches.

## Documents

### Study results

[CARING final publishable summary report\\_fixed.pdf](#)(1.53 MB)

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## 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.

## Conflicts of interest of investigators

## Data sources

### Data source(s)

Clinical Practice Research Datalink

Danish registries (access/analysis)

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### Data source(s), other

National Health Registries Finland, National Health Registries Sweden, NorPD

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### Data sources (types)

[Administrative healthcare records \(e.g., claims\)](#)

[Drug dispensing/prescription data](#)

[Electronic healthcare records \(EHR\)](#)

## 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