# CAncer Risk and INsulin analoGues (CARING) project

**First published:** 10/12/2013
**Last updated:** 23/04/2024

Study | Finalised

## Administrative details

**PURI**
https://redirect.ema.europa.eu/resource/11823

**EU PAS number**
EUPAS5383

**Study ID**
11823

**DARWIN EU® study**
No

**Study countries**
Denmark
Finland
Netherlands
Norway
Sweden

**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.

**Study status**
Finalised

# Research institution 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**
Marie L De Bruin
Study contact

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**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

**Study start date**
Planned:
01/11/2011
Actual:
01/11/2011

**Data analysis start date**
Planned:
01/08/2014
Actual:
01/08/2014

**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

**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:**
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

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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.

**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)

# Data management

## ENCePP Seal

**Conflicts of interest of investigators**
Acknowledgement.pdf(61.42 KB)

## Data sources

**Data source(s)**
Clinical Practice Research Datalink
Danish registries (access/analysis)

**Data source(s), other**
National Health Registries Finland, National Health Registries Sweden, NorPD

**Data sources (types)**
Administrative data (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

**Check completeness**
Unknown

**Check stability**
Unknown

**Check logical consistency**
Unknown

## Data characterisation

**Data characterisation conducted**
No