CAncer Risk and INsulin analoGues (CARING) project

First published: 10/12/2013

Last updated: 23/04/2024

Study Finalised

Administrative details

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 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

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Network | ENCePP partner

Contact details

Study institution contact

Marie L De Bruin m.l.debruin@uu.nl

Study contact

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

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

INSULINS AND ANALOGUES

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)

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

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

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 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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No