ISICA - Case-Control Study on the Risk of Breast Cancer through Insulin Use

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General

Identification

Detailed name	Case-Control Study on the Risk of Breast Cancer through Insulin Use
Sign or acronym	ISICA

General Aspects

Medical area	Cancer research Endocrinology and metabolism Gynecology/ obstetrics
Pathology (details)	Breast cancer; diabetes
Health determinants	Medicine
Keywords	hormone treatment, insulin, glargine, aspart, lispro, cancer, diabetes, contraception

Scientific investigator(s) (Contact)

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Unit	C121-SC of Vie-Pharma fourth group; U657 Pharmacoepidemiology and Evaluation of the Impact of Health Products on the Population? Pasteur Institute
Organization	La-Ser
Collaborations	
Funding	
Funding status	Private
Details	Sanofi-Aventis, La-Ser
Governance of the database	
Sponsor(s) or organisation(s) responsible	Sanofi-Aventis
Organisation status	Private
Sponsor(s) or organisation(s) responsible	La-Ser
Organisation status	Private
Additional contact	
Main features	
Type of database	
Type of database	Study databases
Study databases (details)	Case control study
Database recruitment is carried out by an intermediary	A selection of health institutions and services
Database recruitment is is made on the basis of:	Medication(s) taken
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	The case-control study was conducted using data collected from 92 major breast cancer treatment centres throughout France, United Kingdom and

	Canada, as well as data from treating physicians, prescriptions and the patients themselves in order to minimise bias. 775 patients were selected from the hospital records for 40,000 patients diagnosed with breast cancer between 01 January 2008 and 30 June 2009 (89% primary invasive cancer, 47% TNM 1, 30% TNM2, 64% luminal tumours). Out of these 40,000 patients, diabetes cases were identified from anaesthesia records and confirmation of the disease by the patients themselves. 41% of these patients were eligibles and participated in the study. In all, 6.2% were living and being treated for diabetes. Cancer-free diabetic controls were enrolled by their physicians (582 physicians) and matched according to age, recruitment date, country or region of origin, type of diabetes and management type.
Database objective	
Main objective	The aim is to assess the possible relation between using individual insulins (duration of exposure, administered dosage) and increased breast cancer risk.
Inclusion criteria	For case subjects: ? Breast cancer diagnosed between 01 January 2008 and 30 June 2009 ? Diabetes confirmed by the patient and anaesthesia records. For controls: ? No breast cancer ? Diabetes confirmed by the patient and anaesthesia records
Population type	
Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years)
Population covered	Sick population
Gender	Woman
Geography area	International

Detail of the geography area	France; Canada; United Kingdom
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2008
Date of last collection (YYYY or MM/YYYY)	2009
Size of the database	
Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	3,825
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Declarative data Paraclinical data Biological data
Clinical data (detail)	Direct physical measures
Details of collected clinical data	History of diabetes; risk factor; prescriptions; data; detailed data on diabetes (type, age at diagnosis, duration, antidiabetes treatments); complications (renal, vascular, ophthalmological, and neurological). Information on history of breast and ovarian cancer; insulin therapy (glargine, aspart, lispro, and human insulin); hormone replacement therapy; motherhood; first menstruation; menopause; breastfeeding and oral contraception. Exposure to insulin.
Declarative data (detail)	Phone interview
Details of collected declarative data	Education; socioeconomic status; smoking, alcohol consumption and physical activity
Paraclinical data (detail)	Anaesthesia records for presence of diabetes.
Biological data (detail)	HbA1c
Presence of a biobank	No

Health parameters studied	Health event/morbidity Health care consumption and services
Care consumption (detail)	Medicines consumption
Procedures	
Participant monitoring	No
Links to administrative sources	No
Promotion and access	
Promotion	
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/23949559
Link to the document	http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2810%2961374-8/fulltext
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Contact the scientist in charge.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only