## EGIR-RISC - Relationship between insulin sensitivity and cardiovascular disease

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General	
Identification	
Detailed name	Relationship between insulin sensitivity and cardiovascular disease
Sign or acronym	EGIR-RISC
General Aspects	
Medical area	Endocrinology and metabolism
Study in connection with Covid- 19	No
Health determinants	Addictions Lifestyle and behavior Social and psychosocial factors
Scientific investigator(s) (Contact)	
Name of the director	Balkau
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Organization	Inserm
Name of the director	Ferrannini
Surname	Ele
Collaborations	
Funding	
Funding status	Mixed
Details	Financement européen public, AstraZeneca, Merck

Governance of the database	
Sponsor(s) or organisation(s) responsible	Centre de Recherche en Nutrition Humaine de Lyon (CRNHL)
Organisation status	Public
Additional contact	
Main features	
Type of database	
Type of database	Study databases
Study databases (details)	Cohort study
Database recruitment is carried out by an intermediary	A selection of health institutions and services
Database recruitment is carried out as part of an interventional study	No
Database objective	
Main objective	Main objective: study of insulin resistance and atherosclerosis, determinants of insulin resistance, its evolution on 9 years and consequences, diabetes, cardiovascular diseases and premature death. Secondary objectives: 1. The evaluation of insulin resistance and its association with cardiovascular diseases 2. Identification of genetic and environmental factors linked to insulin resistance 3. The proposition of a model to identify insulin resistance
Inclusion criteria	<ul> <li>Aged between 30 and 60 years</li> <li>Good general health condition</li> <li>No symptoms of cardiovascular diseases</li> <li>blood pressure inferior to 170/90 mm Hg</li> <li>Total cholesterol inferior to 7,8 mmol/l</li> <li>Triglycerides levels inferior to 4,6 mmol/l</li> <li>Plasma glucose level (on an empty stomach and 2 hours after an oral glucose control) inferior to 7,0/11,1 mmol/l</li> <li>No treatment related to diabetes, hypertension or lipid disorders</li> </ul>

Age	Adulthood (25 to 44 years) Adulthood (45 to 64 years)
Population covered	General population
Pathology	
Gender	Male Woman
Geography area	International
Detail of the geography area	Austria, Denmark, Finland, France, Germany, Greece, Netherlands, Ireland, Italy, Sweden, Spain, Switzerland, United Kingdom, Serbia and Montenegro
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2002
Date of last collection (YYYY or MM/YYYY)	2007
Size of the database	
Size of the database (number of individuals)	[1000-10 000[ individuals
Details of the number of individuals	1500
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Declarative data Paraclinical data Biological data
Clinical data (detail)	Medical registration
Declarative data (detail)	Phone interview
Paraclinical data (detail)	Imaging at inclusion and at 3 years : carotid artery scan, Doppler of arm arteries, full body scan in 2 centers (about 150 subjects)

Biological data (detail)	Plasma, serum, leukocyte layer, DNA
Presence of a biobank	Yes
Contents of biobank	Serum Plasma Fluids (saliva, urine, amniotic fluid, ?) DNA
Details of biobank content	At inclusion and at 3 years : blood (lipid profile, genetic characteristics analysis), urine
Health parameters studied	Health event/morbidity Health event/mortality
Procedures	
Data collection method	Interview questionnaire : (1)Life habits, family history (2) occurrence of diseases (3) Lifestyle (personal and family history, tobacco, alcohol, peripheral arterial disease, angina (4) clinical signs or symptoms, diabetes ro weight variation since the examinations (5) Clinical signs or symptoms of cardiovascular diseases, diabetes or weight variation since the examinations, sleep and depression. Clinical examination : (6) Anthropometric measures, blood pressure, ECB, "body-fat" measure by biometrical impedance analysis, hyperinsulinemic-euglycemic clamp, glucose tolerance test, glucose test IV, quantity and quality evaluation of physical activity (7) Anthropometric measures, blood pressure, ECB, "body-fat" measure by biometrical impedance analysis, glucose tolerance test, glucose test IV
Participant monitoring	Yes
Details on monitoring of participants	Follow-up questionnaire
Links to administrative sources	No
Promotion and access	
Promotion	
Link to the document	http://www.hal.inserm.fr/RISC_STUDY
Description	List of publications in HAL
Link to the document	<u>http://www.ncbi.nlm.nih.gov/pubmed/?</u> <u>term=%28Balkau[Author]%29+AND+%28Risc+OR</u> <u>+%22Risk+study%22%29+OR+20660046[uid]</u>

Description	List of publications in Pubmed
Access	
Terms of data access (charter for data provision, format of data, availability delay)	For data access, please submit a written request to the "project management board". Diffusion : oral communications during congresses, published articles, press releases, diffusion to general practitioners and diabetologists, newspapers
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only