PROOF - Prospective evaluation of Autonomic Nervous System (ANS) as a prognostic indicator of cardiovascular and cerebrovascular event in a cohort

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General

Identification

Detailed name	Prospective evaluation of Autonomic Nervous System (ANS) as a prognostic indicator of cardiovascular and cerebrovascular event in a cohort
Sign or acronym	PROOF
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL (15/11/2000)

General Aspects

Medical area	Cardiology Geriatrics Neurology
Health determinants	Genetic
Keywords	autonomic nervous system (ANS), heart rate variability, baroreflex, blood pressure variability, Prevention, epidemiology, sleep

Scientific investigator(s) (Contact)

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Organization	CENTRE HOSPITALIER UNIVERSITAIRE DE

Collaborations

Details	Other related cohorts: 1) Also in charge of the analysis of the activity of ANS in the Sapaldia cohort (Swiss cohort study on air pollution and lung diseases in adults). 2) Aube cohort: ANS evolution after normal or premature birth and cognitive evolution.

Funding

Funding status	Mixed
Details	- PHRC National PROOF, 1999- PHRC National Synapse, 2022- PHRC Régional Telamons, 2003- Industrie pharmaceutique: Laboratoire Servier (Neuropsychologie)- Industrie, Ingenierie SNA: Société Novacor (Cifre)- Association Synapse: association créée par les sujets de l'étude pour soutenir le projet. - TGIR cohortes 2008 (INSERM)

Governance of the database

Sponsor(s) or organisation(s) responsible	CHU St Etienne
Organisation status	Public
Sponsor(s) or organisation(s) responsible	PRES de LYON
Organisation status	Public
Sponsor(s) or organisation(s) responsible	Université Jean Monnet
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 population file
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	Form the electoral list of the city of Saint. Etienne

Database objective

Main objective	Evaluate on a prospective basis the predictive value of ANS activity, and its decline during the follow-up, on the occurrence of serious cerebral events, and on mortality all cause considered, in a general population of homogeneous age, 65 at inclusion.

Secondary objectives have been defined, analyzing the association between ANS and:
1) The presence and severity of cerebrovascular accidents at NRM imaging;
2) Neuropsychological performances;
3) Classic cardiovascular risk factors;
4) Genetic of the specific receptors of the neurotransmitters directly implied; |

	5) Sleep respiratory pathologies; 6) Realization of temporal analysis to determine chronological sequences of the decline of ANS activity and pathological conditions occurrence, including emerging conditions, such as sleep respiratory pathologies.
Inclusion criteria	- 65 ages old subjects at inclusion, and registered on the electoral lists of the city of St.Etienne. - Subjects who did not have a myocardial infarction or a preceding cerebrovascular accident. - Subjects not insulin-dependent

Population type

Age	Elderly (65 to 79 years) Great age (80 years and more)
Population covered	General population
Pathology	
Gender	Male Woman
Geography area	Local
French regions covered by the database	Auvergne Rhône-Alpes
Detail of the geography area	City of Saint-Etienne

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	01/2001
Date of last collection (YYYY or MM/YYYY)	01/2015

Size of the database

Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	1011

Data

Database activity	Current data collection
Type of data collected	Clinical data Declarative data Paraclinical data Biological data
Clinical data (detail)	Direct physical measures Medical registration
Details of collected clinical data	Clinical examination at inclusion and every 2 years during the follow-up. Information collected through the clinical examination: 1) School data 2) Neuropsychological check: - Grober and Buschke; - Benton; - Digit substitution st; - Baddeley's dual task; -Trail marking test; - Stroop; - Wais; - MMSE; 3) Depression (QD2A) 4) Anxiety (Goldberg) 5) Sleep: St. Mary's hospital questionnaire 6) Sleep: Pittsburg questionnaire
Declarative data (detail)	Paper self-questionnaire Face to face interview
Details of collected declarative data	Clinical examination at inclusion and every 2 years during the follow-up. Information collected through the clinical examination: 1) School data 2) Neuropsychological check: - Grober and Buschke; - Benton; - Digit substitution st; - Baddeley's dual task; -Trail marking test; - Stroop; - Wais; - MMSE; 3) Depression (QD2A) 4) Anxiety (Goldberg) 5) Sleep: St. Mary's hospital questionnaire 6) Sleep: Pittsburg questionnaire
Paraclinical data (detail)	Cerebral MRI with a visual evaluation and a quantity analysis (cerebral morphometry for three-dimensional reconstruction), polysomnography functional respiratory exploration, measure of muscular and fat mass, quantitative computed tomography
Biological data (detail)	Blood biology: classic cardiovascular risk factors, inflammation markers, hormones, vitamin D
Presence of a biobank	Yes
Contents of biobank	Serum DNA
Details of biobank content	Seurm bank, DNA bank
Health parameters studied	Health event/morbidity Health event/mortality Others

Other (detail)	Sleep quality, biological inflammatory and hormonal check, genetic check

Procedures

Data collection method	Data have been collected during 5 check-ups, check-ups 1 and 4 are completed, check-ups 2, 3 and 5 are partials (neither cerebral NRM nor neuropsychological check).Clinical data collected concern: - Neuropsychological check analyzing memory, executive and dysexecutive functions (GROBER, BENTON, DSST, BADDELEY, TMT, STROOP, FLUENCIES, WAIS, MMSE)- Depression (QD2A)- Anxiety (GOLDBERG)- Ambulatory blood pressure monitoring, MAPA- HOLTER ECG- Elasticity of arterial walls- Baroreflex- Genetic check- Questionnaire on the existence and severity of restless legs syndrome- Sleep quality questionnaire: St. Mary's hospital and PittsburgSelf-questionnaire data concern:- Evaluation of daily physical activity- Sleep quality (BERLIN, EPWORTH)- Life quality- Urinary disorders (DITROVIE, MHU)Data collected through the interview concern family and personal history (age of menopause, cardiovascular history, personal history, family history, treatments in progress, weight, height, waist/hips circumference, stature, tobacco, alcohol habitudes)
Classifications used	Coherence request after computer data entry. Missing data checked back to the original file or asked back to the patient or a third. Doctors and Subjects remainders for follow-up visits. Internal and external quality audit reports. Internal audit frequency: Statistics, by data themes. External audit frequency: 3. Patients receive information about the use of their data.
Participant monitoring	Yes
Details on monitoring of participants	15 years
Links to administrative sources	No

Promotion and access

Promotion

Link to the document	http://tinyurl.com/Pubmed-Cohorte-PROOF
Description	List of publications in Pubmed

Link to the document	Proof_Liste_from EndNote.doc
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Submit a demand to the director of the SNA-EPIS team. Decision by the steering committee. Data utilization possible for academic teams. Contractual access condition: contact the main investigator or a co-investigator. Data utilization available for industrials. Access condition: contact the main investigator.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only