AUBE - Autonomic maturation in neonatal period and early neurologic development: perspective longitudinal cohort study

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Last update : 02/28/2014 | Version : 2 | ID : 3658

General

Identification

Detailed name	Autonomic maturation in neonatal period and early neurologic development: perspective longitudinal cohort study
Sign or acronym	AUBE
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL : 20/07/2009

General Aspects

Medical area	Neurology Pediatrics
Pathology (details)	Physiology

Scientific investigator(s) (Contact)

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Collaborations

Funding

Funding status	Public
Details	PHRC Inter-régional

Governance of the database

Sponsor(s) or organisation(s) responsible	CENTRE HOSPITALIER UNIVERSITAIRE DE SAINT-ETIENNE
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
Additional information regarding sample selection.	Prospective. End of inclusions: 01/09/2011

Database objective

Main objective	Describe the profile of maturation of the autonomic cardiac system (through time and frequency analysis of the heart rate variability from polysomnographic 24 hours records) during the firsts two years of life (0, 6, 12, 18 and 24 months) in a full-term or premature infants cohort. Secondary objectives: - Correlate in this cohort the autonomic status at birth and the neurological psychomotor becoming at 2 years; - Describe autonomic evolution profile during the firsts two years of life; - According to specific pregnancy criteria; - According to morphometry data; - According to respiratory, cardiac, neurological, digestive, infectious neonatal morbidity criteria; - According to the incidence of severe diseases and rhythmic disorders during the two firsts two years of life.
Inclusion criteria	- Every child born at the CHU of Saint Etienne, regardless of the terms of birth, hospitalized in a neonatal unit at the moment of the recording (after 37 corrected weeks in case of prematurity) or at the maternity ward. - Signature of the written consent by the parents or the legal guardians. - Parents or legal guardians, affiliated to social security or right-holder.

Population type

Age	Newborns (birth to 28 days)
Population covered	General population
Gender	Male Woman

Geography area	Local
French regions covered by the database	Auvergne Rhône-Alpes
Detail of the geography area	Saint-Etienne

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	09/2009
Date of last collection (YYYY or MM/YYYY)	08/2013

Size of the database

Size of the database (number of individuals)	[500-1000[individuals
Details of the number of individuals	6400

Data

Database activity	Data collection completed
Type of data collected	Clinical data Declarative data Paraclinical data
Clinical data (detail)	Medical registration
Details of collected clinical data	Clinical examination at inclusion and during the follow-up at 24 months
Declarative data (detail)	Face to face interview
Details of collected declarative data	Clinical examination at inclusion and during the follow-up at 24 months
Paraclinical data (detail)	Sleep-wake polysomnography
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality

Procedures

Data collection method	Self-questionnaire: manually filled paper questionnaire with double data entry.Interviews: direct data entryClinical examinations: direct data entryData collected: - Pregnancy specific criteria demand the following parameters: # Maternal history (origin, maternal age at birth, hypertension)# Prenatal prevention for neonatal respiratory distress syndrome through steroid use# Type of childbirth (caesarean section or vaginal delivery), gestational age# Intrauterine growth retardation# Social and familiar environment: family status, professional activity, education level of the holders of parents responsibility- Neonatal morphometry criteria are represented by weight, size and head circumference of the child at birth, gender.- Neonatal morbidity criteria needs the following medical information:# Intraventricular hemorrhage defined according to the PAPILE36 (cranial ultrasonography) classification# Periventricular leukomalacia (cranial ultrasonography)# Bronchopulmonary dysplasia (defined through an oxygen dependence test at 36 corrected weeks with possibility of saturation maintenance superior to 90% during 3 hours)# Retinopathy of prematurity according to the international classification (dilated fundus examination in indirect ophthalmoscopy, systematically realized among this population)
Quality procedure(s) used	Coherence request after computer data entry. Missing data asked back to the patient or a third. Doctors remainders for follow-up visits. Internal quality audit reports every 6 months. Internal audit frequency: Statistics, by data themes. External audit frequency: 3. EIG declaration (serious adverse effects). Patients receive information about the use of their data.
Participant monitoring	Yes
Details on monitoring of participants	2 years
Links to administrative sources	No

Promotion and access

Promotion

Link to the document	https://www.ncbi.nlm.nih.gov/pubmed/?term=(+((aube+OR+neurologic+development+OR+autonomic+maturation)+AND+(Patural+H%5BAu

	thor%5D+OR+Barthelemy+JC%5BAuthor%5D+OR+Teyssier+G%5BAuthor%5D)+NOT+animal
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Data utilization for academic teams and for industrials to be determined.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only