

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

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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 |
|----------------|--------|

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| Details | PHRC Inter-régional |
|---------|---------------------|

Governance of the database

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| Sponsor(s) or organisation(s) responsible | CENTRE HOSPITALIER UNIVERSITAIRE DE SAINT-ETIENNE |
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| Organisation status | Public |
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Additional contact

Main features

Type of database

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| Type of database | Study databases |
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| 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 | <p>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.</p> <p>Secondary objectives:</p> <ul style="list-style-type: none"> - 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 | <ul style="list-style-type: none"> - 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 |

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| 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 | |

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|---------------------------------------|--|
| Data collection method | <p>Self-questionnaire: manually filled paper questionnaire with double data entry. Interviews: direct data entry. Clinical examinations: direct data entry. Data 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)</p> |
| Quality procedure(s) used | <p>Coherence request after computer data entry. Missing data asked back to the patient or a third. Doctors reminders 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.</p> |
| 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 |

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