Cohorte PC - Prospective study of young patients with bilateral and severe cerebral palsy : incidence and evolution of orthopaedic complications and pain related to these complications

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General

Identification

Detailed name	Prospective study of young patients with bilateral and severe cerebral palsy : incidence and evolution of orthopaedic complications and pain related to these complications
Sign or acronym	Cohorte PC
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL: 910232.

General Aspects

Medical area	Disability/handicap Neurology Pediatrics Physical medicine and rehabilitation Radiology and medical imaging
Health determinants	Lifestyle and behavior Social and psychosocial factors
Others (details)	Cerebral palsy
Keywords	Pain; Children; Cohort; Orthopaedic complications; Epidemiology; Cerebral palsy

Scientific investigator(s) (Contact)

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Organization	Groupement Hospitalier Est, Hospices Civils de

Collaborations

Funding

Funding status	Mixed
Details	ALLP Association Lyonnaise de Logistique Post-Hospitalière (ALLP) 2010 La Fondation Motrice 2008 Le Programme Hospitalier de Recherche Clinique (PHRC) 2009

Governance of the database

Sponsor(s) or organisation(s) responsible	Groupement Hospitalier Est, Hospices Civils de Lyon
Organisation status	Public
Presence of scientific or steering committees	Yes

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.	Patients are recruited among Centres Hospitalo-Universitaires (CHU), Centres Hospitalier Généraux (CH), Institut Médico-Educatif (IME), Instituts d'Education Motrice (IEM), Centres d'Education Motrice (CEM), Services de Soin et d'Education à

	Domicile (SESSAD), Centres d'Action Médico- Sociale Précoce (CAMPS). To avoid a selection bias, it is demanded to each investigator to include all elegible patients of their Sites.

Database objective

Main objective	The primary objective of this cohort study is to establish the incidence of orthopaedic complications (scoliosis and hip joint) depending on patients' age. The secondary objectives are to describe the sequences over time of these complications and the related pain, to explore the impact of nutrition, surgery, asymmetric postures and environmental factors, and to describe the medical and rehabilitative follow-up of these patients.
Inclusion criteria	- Children over 3 and under 10 year-old at inclusion - Cerebral palsy (brain lesion or defect before 2 years of age), with bilateral and severe lesion (level IV or V of GMFCS [Gross Motor Function Classification System]) - Non-progressive cerebral lesion

Population type

Age	Early childhood (2 to 5 years) Childhood (6 to 13 years) Adolescence (13 to 18 years) Adulthood (19 to 24 years)
Population covered	Sick population
Pathology	G80 - Cerebral palsy
Gender	Male Woman
Geography area	National
Detail of the geography area	France + DOM (Reunion Island and Martinique)

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	09/2009
Date of last collection (YYYY or MM/YYYY)	on-going

Size of the database

Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	222 (15/03/2013)

Data

Database activity	Current data collection
Type of data collected	Clinical data Paraclinical data
Clinical data (detail)	Direct physical measures Medical registration
Paraclinical data (detail)	Radiological exam (spinal column and hip radiographies).
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality

Procedures

Data collection method	Data are recorded on Case Report Forms by study investigators, during each annual patients' visits. These visits are part of the usual follow-up care of the patients. Data recorded are based on parents questionning, patient's clinical exam, patient's radiographies, and medical files if needed (medical history, clinical and para-clinical datas,...).
Participant monitoring	Yes
Details on monitoring of participants	There are 10 years of follow-up for the patients, at the rhythm of 1 visit per year. Before each annual visits, a new Case Report Form is sent to investigators, to record datas for the next patient's visit (same model of Case Report Form for all the 10 visits).
Links to administrative sources	No

Promotion and access

Promotion

Link to the document	http://www.em-consulte.com/en/article/855582

Description	
Link to the document	https://www.ncbi.nlm.nih.gov/pubmed/24120244
Description	

Access

Terms of data access (charter for data provision, format of data, availability delay)	- Terms of full database access: not yet discussed. - Terms of partial data access: a manuscript related to the rehabilitation of the 190 first patients included has been submitted for publication.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only