

# 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 Soins 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 eligible 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 questioning, 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