PERICLES - Mild Head Trauma and Post-Concussion Syndrome. Study of Outcome at 5 years.

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General

Identification

Detailed name	Mild Head Trauma and Post-Concussion Syndrome. Study of Outcome at 5 years.
Sign or acronym	PERICLES
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CPP n°2007/49 - 2007-A00807-46 CCP SUD-OUEST ET OUTRE MER III

General Aspects

Medical area	Traumatology
Others (details)	Head trauma, post-concussion syndrome
Keywords	post-concussion syndrome, Prevalence, follow-up, symptoms, predictive factors

Scientific investigator(s) (Contact)

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Unit	U897 PRÉVENTION ET PRISE EN CHARGE DES TRAUMATISMES (Equipe de l'ISPED - Institut de Santé Publique, d'Epidémiologie et de Développement)
Organization	INSERM - Institut National de la Santé et de la

	Recherche
Name of the director	Ribéreau- Gayon
Surname	Régis
Collaborations	
Funding	
Funding status	Mixed
Details	PHRC Local - Fondation Réunica
Governance of the database	
Sponsor(s) or organisation(s) responsible	INSERM - Institut National de la Santé et de la Recherche Médicale
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.	Enrolment request at emergency department
Database objective	
Main objective	To comparatively measure the prevalence of post-concussion symptoms at 5 years and to determine predictive factors.
Inclusion criteria	Upon adult admission to the emergency department of CHU de Bordeaux, requests to participate in the study were made to: - all patients with mild head trauma presenting one of more signs of severity (Glasgow score of 15, 14 or 13). -

	a sample of patients who received a blow to the head without other signs of severity. - case-controls matched according to case age and gender, chosen from patients in the emergency unit for pathologies that did not involve head trauma or potential consequences of the same.
Population type	
Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years)
Population covered	Sick population
Gender	Male Woman
Geography area	Regional
French regions covered by the database	Aquitaine Limousin Poitou-Charentes
Detail of the geography area	Aquitaine
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2008
Date of last collection (YYYY or MM/YYYY)	2008
Size of the database	
Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	3459
Data	
Database activity	Current data collection
Type of data collected	Clinical data Declarative data
Clinical data (detail)	Direct physical measures

Declarative data (detail)	Paper self-questionnaire
Presence of a biobank	Yes
Contents of biobank	Serum
Details of biobank content	The blood sample remainder taken during standard routine treatment was used to measure the level of S100B protein.
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services Quality of life/health perception
Care consumption (detail)	Hospitalization Medical/paramedical consultation

Procedures

Data collection method	Medical examinations and brain CT scans for cases were conducted in the normal course of treatment for people admitted to the emergency department. Participants answered a questionnaire (M0 questionnaire) in order to assess quality of life before the accident and the existence of common functional symptoms during their time in the emergency department. Patients were contacted again at 3 and 12 months (M3 and M12) after enrolment. In order to obtain standardised quantitative information on the patient's status after returning home, the initial M0 questionnaire and M3 and M12 questionnaires were prepared by adapting the 3 questionnaires below: the "Rivermead Post-Concussion Symptoms Questionnaire" (RSQ), the "Rivermead Head Injury Follow Up Questionnaire" and part of the ?Short Form 36 Health Questionnaire? (SF36). The last part of these questionnaires is devoted to the evaluation of post-traumatic stress and disabilities regarding daily life activities.
Participant monitoring	Yes
Details on monitoring of participants	3 and 12 months after enrolment.
Links to administrative sources	No

Promotion and access

Promotion

Access	
Terms of data access (charter for data provision, format of data, availability delay)	Data are available for other researchers in accordance with agreement by the investigating parties.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only