IRM-COMA - Development of Multimodal Resonance Imaging for Outcome Prediction in Coma Patients

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General

Identification

Detailed name	Development of Multimodal Resonance Imaging for Outcome Prediction in Coma Patients
Sign or acronym	IRM-COMA
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	--

General Aspects

Medical area	Radiology and medical imaging
Keywords	Coma

Scientific investigator(s) (Contact)

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Collaborations

Funding

Funding status	Public
Details	ASSISTANCE PUBLIQUE - HÔPITAUX DE PARIS

Governance of the database

Sponsor(s) or organisation(s) responsible	APHP

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	Yes
Details	Performed at individual level
Additional information regarding sample selection.	Prospective Inclusion cut-off date: 01/11/2010
Database objective	
Main objective	To develop a composite score able to predict the awakening of coma patients following a severe cranial trauma. This composite score will be built from the results of the multimodal MRI (quantified indicator) in combination with clinical covariables e.g. age of the patient, the mechanism of the accident (high versus low speed), initial Glasgow score, clinical examination data at time of MRI and comorbidities. The composite score will aim to predict the outcome of patients at 1 year, evaluated by one of the following three categories: favourable outcome (GOS 3+, 4, and 5) and unfavourable outcome (GOS 1, 2, and 3-). The GOS 3- score has been defined as severe disability with minimally conscious state and GOS 3+ score as severe disability excluding cognitive sequelae. - To evaluate the relevance of the composite score to predict the clinical outcome at 1 year assessed by the Rankin score, GOS and the disability rating scale (DRS). - To analyse intra and inter-observer reproducibility study of the analysis of the various sequences.
Inclusion criteria	1, Adults covered by a social security scheme. 2. Hospitalised in intensive care and requiring artificial ventilation following a severe cranial trauma, an ischaemic or haemorrhagic cerebrovascular accident or a cerebral anoxia. 3. Not answering

	simple orders at least 7 days after ictus. 4. Receiving an amount of sedatives and not being able to explain the coma. 5. Having a standardised intracranial pressure (? 15 mm Hg) and in absence of severe haemodynamic or respiratory failure so that the MRI does not represent any additional danger. - severe haemodynamic failure is defined as a circulatory condition requiring administration of high-dose catecholamines (noradrenaline > 3 mg/h and/or dobutamine > 10 µg/kg/min); - Severe respiratory failure is defined as the use of FiO2 > 60% combined with positive expiratory pressure > 10 cm H2O.
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	International
Detail of the geography area	France, Belgium, Switzerland, Lyon, Lille, Paris, Nancy, Marseille, Montpellier, Grenoble, Rouen, Bordeaux, Liège and Geneva.
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	10/2006
Date of last collection (YYYY or MM/YYYY)	11/2011
Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	- 250: traumatisés crâniens - 150: autres causes de coma (accident vasculaire cérébral ischémique ou hémorragique)
Data	
Database activity	Current data collection

Type of data collected	Declarative data Paraclinical data
Declarative data (detail)	Phone interview
Paraclinical data (detail)	Imaging
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality

Procedures

Data collection method	Interview: direct input
Participant monitoring	Yes
Details on monitoring of participants	Duration: 1 year
Links to administrative sources	No

Promotion and access

Promotion

Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/23135261
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/24471392
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/22363051
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/22366842

Access

Terms of data access (charter for data provision, format of data, availability delay)	To be decided if data may be used by academic teams Data may not be used by industrial teams
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only