

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

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Last update : 08/07/2014 | Version : 1 | ID : 60185

## General

### Identification

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

|              |                               |
|--------------|-------------------------------|
| Medical area | Radiology and medical imaging |
|--------------|-------------------------------|

|          |      |
|----------|------|
| Keywords | Coma |
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### Scientific investigator(s) (Contact)

|                      |           |
|----------------------|-----------|
| Name of the director | Puybasset |
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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 |
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|------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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                                                         | <p>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.</p> |
| Inclusion criteria                                                     | <p>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</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |

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 ( $\leq 15$  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  $> 10$   $\mu$ g/kg/min); - Severe respiratory failure is defined as the use of FiO<sub>2</sub>  $> 60\%$  combined with positive expiratory pressure  $> 10$  cm H<sub>2</sub>O.

| Population type                              |                                                                                                                               |
|----------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|
| Age                                          | Adulthood (19 to 24 years)<br>Adulthood (25 to 44 years)<br>Adulthood (45 to 64 years)                                        |
| Population covered                           | Sick population                                                                                                               |
| Gender                                       | Male<br>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<br>Paraclinical data                                                                 |
| Declarative data (detail)                                                             | Phone interview                                                                                       |
| Paraclinical data (detail)                                                            | Imaging                                                                                               |
| Presence of a biobank                                                                 | No                                                                                                    |
| Health parameters studied                                                             | Health event/morbidity<br>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                                                                  | <a href="http://www.ncbi.nlm.nih.gov/pubmed/23135261">http://www.ncbi.nlm.nih.gov/pubmed/23135261</a> |
| Link to the document                                                                  | <a href="http://www.ncbi.nlm.nih.gov/pubmed/24471392">http://www.ncbi.nlm.nih.gov/pubmed/24471392</a> |
| Link to the document                                                                  | <a href="http://www.ncbi.nlm.nih.gov/pubmed/22363051">http://www.ncbi.nlm.nih.gov/pubmed/22363051</a> |
| Link to the document                                                                  | <a href="http://www.ncbi.nlm.nih.gov/pubmed/22366842">http://www.ncbi.nlm.nih.gov/pubmed/22366842</a> |
| 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<br>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                                                                       |