

# TOMENF - Iatrogenic risks associated with CT scans received in childhood

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| General                                                                                                                  |                                                                                                                                                                                          |
|--------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Identification                                                                                                           |                                                                                                                                                                                          |
| Detailed name                                                                                                            | Iatrogenic risks associated with CT scans received in childhood                                                                                                                          |
| Sign or acronym                                                                                                          | TOMENF                                                                                                                                                                                   |
| CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation | CNIL: 10/11/2009, number 1347141), CCTIRS (or French IRB) (11/06/2009, number 09.271).                                                                                                   |
| General Aspects                                                                                                          |                                                                                                                                                                                          |
| Medical area                                                                                                             | Cancer research<br>Radiology and medical imaging                                                                                                                                         |
| Health determinants                                                                                                      | Iatrogenic                                                                                                                                                                               |
| Others (details)                                                                                                         | all types of cancer and other radiation-induced diseases                                                                                                                                 |
| Keywords                                                                                                                 | CT scan, medical exposure, iatrogenic effects of radiation, low doses of ionizing radiation, cerebrovascular disease, dosimetry, childhood, risk factors, cohort, cardiovascular disease |
| Scientific investigator(s)<br>(Contact)                                                                                  |                                                                                                                                                                                          |
| Name of the director                                                                                                     | De Vathaire                                                                                                                                                                              |
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| Unit                                                                                                                     | Equipe-3 d'Epidémiologie des radiations- CESP- UMR                                                                                                                                       |

|              |                                                           |
|--------------|-----------------------------------------------------------|
| Organization | INSERM - Institut National de la Santé et de la Recherche |
|--------------|-----------------------------------------------------------|

## Collaborations

## Funding

|                |       |
|----------------|-------|
| Funding status | Mixed |
|----------------|-------|

|         |                                                                                |
|---------|--------------------------------------------------------------------------------|
| Details | INSERM, European Commission (FP7-EURATOM-FISSION), Electricity of France (EDF) |
|---------|--------------------------------------------------------------------------------|

## 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 is made on the basis of: | Another treatment or procedure |
|--------------------------------------------------|--------------------------------|

|                                                                        |    |
|------------------------------------------------------------------------|----|
| Database recruitment is carried out as part of an interventional study | No |
|------------------------------------------------------------------------|----|

|                                                    |                                                                                                                                                                                                                                                                                                                                                                                                             |
|----------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Additional information regarding sample selection. | This cohort study is based on data collection within French radiology departments. Cases are recorded in selected centers in France, according to the following criteria: radiology services with computerized medical records and with a significant activity in paediatrics (about a dozen center). Currently available data indicate that the total number of inclusion should be between 20 and 30,000. |
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## Database objective

|                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|--------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Main objective                             | <p>The main objective is to identify group of children who received CT scan and to study the long-term effects of the radiation in order to gain knowledge about all potential iatrogenic effects after exposure to CT scan in childhood by means of a cohort study.</p> <p>The study aims to:</p> <ul style="list-style-type: none"> <li>- identify a potential risk of radiation-induced cancer after CT scan in childhood, and quantify if any;</li> <li>- identify the factors affecting this potential risk, namely, the relationship with the dose received by the organ, the percentage of the irradiated body, age at CT scan, gender and possibly other carcinogenic factors.</li> </ul> <p>Secondary objectives are to identify potential risks of other radiation-induced diseases such as cerebrovascular and cardiovascular diseases and quantify them if they exist.</p> |
| Inclusion criteria                         | <ul style="list-style-type: none"> <li>- Child under 15 years at the CT scan</li> <li>- CT scan received for reasons other than suspicion of tumor</li> <li>- CT scan in the period 1998-2008</li> <li>- Children whose main residence is in France at the time of CT scan</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Population type                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Age                                        | <p>Infant (28 days to 2 years)</p> <p>Early childhood (2 to 5 years)</p> <p>Childhood (6 to 13 years)</p> <p>Adolescence (13 to 18 years)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Population covered                         | General population                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Gender                                     | <p>Male</p> <p>Woman</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Geography area                             | National                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Detail of the geography area               | France (French centers of radiology with computerized medical records )                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Data collection                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Dates                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Date of first collection (YYYY or MM/YYYY) | 2009                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Size of the database                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |

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|----------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Size of the database (number of individuals) | [10 000-20 000[ individuals                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Details of the number of individuals         | 11 000                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Data                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Database activity                            | Current data collection                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Type of data collected                       | Clinical data<br>Paraclinical data<br>Administrative data                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Clinical data (detail)                       | Direct physical measures<br>Medical registration                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Paraclinical data (detail)                   | CT scan images and related computed tomography (date, pattern, underlying pathology, viewing area, availability of protocol, contrast, dose delivered, file dicom image scanners feature data protocols examinations).                                                                                                                                                                                                                                                                              |
| Administrative data (detail)                 | Vital status and cause of death, cancer cases                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Presence of a biobank                        | No                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Health parameters studied                    | Health event/morbidity<br>Health event/mortality                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Procedures                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Data collection method                       | The cohort consists of consultation of the radiology centers participating computerized medical records. Identification and anthropometric data, the pattern of the CT scan and dosimetric data are collected to estimate the CT dose. These data are then interconnected with consultation and cross medico-administrative databases providing information on vital status, causes of deaths and cancers. The methodology used is that of a retrospective cohort study with prospective follow-up. |
| Participant monitoring                       | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Links to administrative sources              | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Linked administrative sources (detail)       | The vital status, causes of deaths and cancer cases are updated every five years. The introduction of another form of monitoring, such as the use of the medical facilities of the French Health Insurance Information System will soon considered because it                                                                                                                                                                                                                                       |

is essential to extend the monitoring of these children into adulthood. Follow-up with no end time.

## Promotion and access

### Promotion

### Access

Terms of data access (charter for data provision, format of data, availability delay)

This study is the French part of an international study (CHILD-MED-RAD: Cohort studies of children with substantial businesses diagnostic medical exposures). The International Agency for Research on Cancer (IARC) of the WHO (Lyon) has access to non-personal data.  
Terms of access to all or part of the data base is being set for outside teams who wish to study from these data.

Access to aggregated data

Access on specific project only

Access to individual data

Access on specific project only