

EpiHadron - Incidence study with population of Rhone-Alpes region of cancers eligible for hadrontherapy by proton or carbon ions. Description of Tumors and patients characteristics

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General

Identification

Detailed name	Incidence study with population of Rhone-Alpes region of cancers eligible for hadrontherapy by proton or carbon ions. Description of Tumors and patients characteristics
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Sign or acronym	EpiHadron
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CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL : 1435497
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General Aspects

Medical area	Cancer research Otolaryngology or ENT
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Health determinants	Iatrogenic
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Keywords	hadrontherapy, descriptive prospective survey, evaluation., Epidemiology, incidence, ENT
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Scientific investigator(s) (Contact)

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Organization	Centre Léon Bérard

Name of the director	Patin
Surname	Stéphanie
Organization	GCS (Groupment de Coopération Sanitaire) ETOILE

Collaborations

Funding

Funding status Private

Details GCS ETOILE

Governance of the database

Sponsor(s) or organisation(s) responsible Promoteur : GCS ETOILE, 60 avenue Rockefeller, 69008, Lyon.

Organisation status Public

Additional contact

Main features

Type of database

Type of database Study databases

Study databases (details) Longitudinal study (except cohorts)

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

Database objective

Main objective The main objective is to evaluate in the Rhône-Alpes region the incidence of cancers that have an indication eligible for treatment with hadrontherapy by proton or carbon ions.

Inclusion criteria
Type of tumors to identify:
A list of the main indications for hadrontherapy by protons and by carbon ions (Appendix 1: list of indications) was developed by experts using data from literature prioritized according to an "evidence based medicine" type analysis and based on rendered or expected service criteria (survival and quality of life), (Appendix 2: Literature review method).

Criteria for "patient" inclusion
The study will be carried out with adult and child subjects, with no age limit, who have indications of

hadrontherapy, whose dossiers were able to be discussed by experts at a preliminary pluridisciplinary concertation meeting (RCP). Subjects must have a general and psychological condition that is compatible with hadrontherapy (good compliance, possible follow-up, accept to travel where applicable) and absence of co-morbidities that are life-threatening.

Criteria for "tumor" inclusion

The characteristics common to the pathologies to be identified are as follows:

Inoperable tumors, which belong to a pathological group recognized as radio-resistant, at the early stage of development (locoregional stage) or recurring or local relapse, with a low metastatic potential or with an M+ dissemination controlled by medical treatments.

Criteria for exclusion

Tumors: Choroidal melanomas are excluded from the study.

Patients: General or psychological condition that is not compatible or threatening co-morbidities.

Population type

Age	Newborns (birth to 28 days) Infant (28 days to 2 years) Early childhood (2 to 5 years) Childhood (6 to 13 years) Adolescence (13 to 18 years) Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years) Great age (80 years and more)
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Population covered	Sick population
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Gender	Male Woman
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Geography area	Regional
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French regions covered by the database	Auvergne Rhône-Alpes
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Detail of the geography area	Rhône-Alpes
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Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2010
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Date of last collection (YYYY or MM/YYYY)	2012
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Size of the database

Size of the database (number of individuals)	[500-1000[individuals
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Details of the number of individuals	800
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Data

Database activity	Current data collection
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Type of data collected	Clinical data Biological data Administrative data
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Clinical data (detail)	Medical registration
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Biological data (detail)	anatomopathological results
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Administrative data (detail)	monogram
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Presence of a biobank	No
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Health parameters studied	Health event/morbidity Health care consumption and services Others
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Care consumption (detail)	Hospitalization Medical/paramedical consultation
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Other (detail)	1) Characteristics of the tumors: therapeutic status, recurrence situation, initial stage of the tumor, treatments received before recurrence, timeframe recurrence occurred, current stage of the tumor, ICD 10 code, ICDO histological type, treatment prior to preliminary pluridisciplinary concertation (RCP), site of surgery and the margins, pTNM, external radiotherapy, therapeutic strategy considered by the RCP; 2) Characteristics of the patients; 3) Care of the preliminary pluridisciplinary concertation meeting type.
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Procedures

Data collection method	prospective, continuous
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Participant monitoring	No
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Links to administrative sources	No
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Promotion and access

Promotion

Link to the document	http://tinyurl.com/Hal-EPIHADRON
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Description	List of publications in HAL
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Link to the document	http://tinyurl.com/Pubmed-Publis-EPIHADRON
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Description	List of publications in Pubmed
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Access

Terms of data access (charter for data provision, format of data, availability delay)	publication of articles
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Access to aggregated data	Access on specific project only
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Access to individual data	Access on specific project only
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