

- Cohort of High-Grade AIN3 Anal Dysplasia

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General

Identification

Detailed name	Cohort of High-Grade AIN3 Anal Dysplasia
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	Avis CCTIRS n°12239 (11 avril 2012), accord CNIL n° 912217 (10/10/2012), avis du Comité d'éthique indépendant GHU Nord n° 12-032 (19/04/2012).

General Aspects

Medical area	Cancer research Gastroenterology et hepatology Infectious diseases
Health determinants	Lifestyle and behavior
Keywords	High-grade anal dysplasia (AIN3), epidermoid carcinoma of the anus, risk factors

Scientific investigator(s) (Contact)

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Unit	Département Epidémiologie et Recherche clinique
Organization	APHP.Nord Université de Paris, Hôpital Bichat Claude Bernard

Collaborations

Participation in projects,	Yes
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Funding

Funding status	Mixed
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Details	COMAD, SNFCP, SIDACTION, La Ligue, MSD
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Governance of the database

Sponsor(s) or organisation(s) responsible	APHP
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Organisation status	Public
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Presence of scientific or steering committees	Yes
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Additional contact

Name of the contact	Abramowitz
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Surname	Laurent
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Unit	Service d'Hépatogastro-entérologie
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Organization	APHP.Nord Université de Paris, Hôpital Bichat Claude Bernard
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Main features

Type of database

Type of database	Study databases
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Study databases (details)	Cohort study
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Database recruitment is carried out by an intermediary	A selection of health institutions and services
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Database recruitment is carried out as part of an interventional study	No
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Additional information regarding sample selection.	Centres participating in the study, hospitals or private practices, are the vast majority of French centres involved in the diagnosis and treatment of
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anal diseases, particularly squamous cell carcinoma of the anus. Anatomopathological data from these centres will allow the most comprehensive retrospective identification of anal AIN3 lesion cases and their oncological complications since 2000. Study set up in 2013. Inclusions are interrupted in June 2020 (achievement of the scheduled number of patients). Follow-up still ongoing.

Database objective

Main objective

The main objective of the study is the evaluation of 3-year anal carcinoma incidence in patients with anal AIN3 lesions. Secondary objectives are: - To identify patients with an anal AIN3 lesion, risk factors (demographical data, HIV status...), treatment factors (type of therapeutic treatment), virological and immunological factors (HPV genotype, presence or non-presence of P16 and Ki67 proteins) associated with the onset of epidermoid carcinoma of the anus.- To identify if the presence of P16/Ki67 factors and high risk HPV virus is associated with an increased risk of recurrent AIN3 lesions and if this is the case for high-grade dysplasia of the cervix. - To estimate the proportion of adherent patients, and to identify factors associated with compliance monitoring (demographics, HIV status, type of treatment undertaken ...) - to assess the overall feeling of patients towards anal AIN3 lesion therapeutic care.

Inclusion criteria

Anal AIN3 lesion diagnosed by histology: - a posteriori for patients with a history of anal AIN3 complicated or not complicated by anal cancer. These cases will be identified from data bases of anatomopathology laboratories in hospitals since 1st January 2000. - patients consulting a proctologist at time of diagnosis for first dysplastic anal AIN3 lesion.

Population type

Age

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)

Population covered

Sick population

Pathology

D01 - Carcinoma in situ of other and unspecified digestive organs

Gender	Male Woman
Geography area	National
Detail of the geography area	35 specialist patient treatment centres throughout metropolitan France
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2000
Date of last collection (YYYY or MM/YYYY)	09/2019
Size of the database	
Size of the database (number of individuals)	[500-1000[individuals
Details of the number of individuals	865
Data	
Database activity	Current data collection
Type of data collected	Clinical data Paraclinical data Biological data
Clinical data (detail)	Direct physical measures Medical registration
Paraclinical data (detail)	Standard or high resolution anoscopy (according to usual practices)
Biological data (detail)	Biological components: - anal smear - biopsy of lesions - cytology - histological analysis - Ki67 and P16 protein research - research and genotyping of HPV virus
Presence of a biobank	Yes
Contents of biobank	Others
Details of biobank content	Other: anal smear. Samples taken during treatment are stored in the CERBA laboratory.

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 Medicines consumption
Procedures	
Data collection method	Data collected retrospectively and prospectively by the proctologist in charge of the medical examination and follow-up consultation.
Quality procedure(s) used	monthly data management, queries on missing data or inconsistencies, median follow-up
Participant monitoring	Yes
Monitoring procedures	Monitoring by contact with the referring doctor
Details on monitoring of participants	Follow-up duration is a minimum of 3 years
Followed pathology	C00-C75 - Malignant neoplasms, stated or presumed to be primary, of specified sites, except of lymphoid, haematopoietic and related tissue D01 - Carcinoma in situ of other and unspecified digestive organs
Links to administrative sources	No
Promotion and access	
Promotion	
Access	
Presence of document that lists variables and coding procedures	Yes
Terms of data access (charter for data provision, format of data, availability delay)	Contact the scientist in charge
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only