SAPHIR - Study on Antifungal Prophylaxis in High Risk Hematology patients

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General

Identification

Detailed name	Study on Antifungal Prophylaxis in High Risk Hematology patients
Sign or acronym	SAPHIR

General Aspects

Medical area	Hematology

Scientific investigator(s) (Contact)

Name of the director	ALLAVOINE
Surname	Thierry

Collaborations

Funding

Funding status	Private
Details	MSD France

Governance of the database

Sponsor(s) or organisation(s) responsible	MSD France
Organisation status	Private

Additional contact

Main features

Type of database

Type of database	Study databases

Database objective

Main objective	The primary objective is to describe, in French hematological services, the monitoring and the therapeutic management of patients at high risk of IFDs under AF prophylaxis in real life clinical practices (imaging and laboratory exams for IFD diagnoses and surveillance, AF therapy prescribed, Therapeutic Drug Monitoring performed, facility environment).
Inclusion criteria	Inclusion criteria : In each center, all patients meeting the following criteria will be solicited to participate to the study. 1. Male or female adult patient, aged of 18 years old or more 2. Subject undergoing myelosuppressive intensive chemotherapy for AML with present or expected profound and prolonged neutropenia* 3. Initiating a systemic** antifungal prophylaxis (J0 = 1St day of administration of the AF) 4. Accepting to participate to the study * : Profound and prolonged neutropenia is define by an absolute value of neutrophils < 500/mm3 during 10 days ** : A systemic antifungal prophylaxis is defined by a treatment provided per os or in i.v. An oral suspension can be considered as a systemic use in function of the dose used (example: fluconazole ? 800mg/j is considered as a systemic treatment) Exclusion criteria : Patients meeting the following criteria should not be included 1. Patient refusing to participate to the study. All inclusion and exclusion criteria will be reviewed by the investigator or qualified designee to ensure that the subject qualifies for the study.
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	II - Neoplasms
Gender	Male Woman

Geography area	National
Detail of the geography area	No details
Data collection	
Dates	
Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	400
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Declarative data
Presence of a biobank	No
Procedures	
Participant monitoring	Yes
Monitoring procedures	Monitoring by contact with the referring doctor
Links to administrative sources	Yes
Linked administrative sources (detail)	InVS
Promotion and access	
Promotion	
Access	
Terms of data access (charter for data provision, format of data, availability delay)	No charte specific to data access
Access to aggregated data	Access not yet planned
Access to individual data	No access