ABSINTHE - Observational study of the therapeutic strategy in the management of acute sinusitis in primary care

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General

Identification

Detailed name	Observational study of the therapeutic strategy in the management of acute sinusitis in primary care
Sign or acronym	ABSINTHE
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CCTI-RS 04.342, CNIL 904410

General Aspects

Medical area	Otolaryngology or ENT
Health determinants	Iatrogenic
Keywords	telithromycin, antibiotic, ENT, Ketek, management, effectiveness, therapeutic strategies, recommendations, pharmacoepidemiology, cohort, Department of Pharmacology, Bordeaux

Scientific investigator(s) (Contact)

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Organization	Université Bordeaux

Collaborations

Funding

Funding status	Mixed
Details	Laboratoire Sanofi-Aventis (soutien inconditionnel) - Sanofi-Aventis (unconditional support)

Governance of the database

Sponsor(s) or organisation(s) responsible	INSERM
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 care professionals
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	A database of general practitioners and non-hospital ENT specialists provided by Wanadoo was used for selection of physicians. General practitioners and ENT specialists were to include prospectively over a period of 4 weeks patients with an episode of acute sinusitis diagnosed according to criteria of the physician. To avoid conducting the study over a period with marked ecological features such as a period of epidemic influenza or respiratory syncytial virus that can interfere with diagnosis and / or treatment of acute sinusitis, the study was conducted over two four-week periods: March / April and September / October. Each physician was to include the first patients meeting the study inclusion criteria (5 during the first wave of inclusion and 6 in the second).

Database objective

Main objective	The study objectives were to describe the

	management of acute sinusitis in real-life conditions of prescription and to evaluate the effectiveness of the initial therapeutic strategy.
Inclusion criteria	Patient consulting for acute sinusitis diagnosed according to criteria of the practitioner; Patient without a previous episode of acute sinusitis during the two months preceding diagnosis; Patient aged 18 years and over; Patient agreeing to participate in the study; Patient not included in a clinical trial (Huriet-Sérusclat); Patient who may be followed for two months; Patient showing no severe active disease (life-threatening in the next three months).
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
Gender	Male Woman
Geography area	National
Detail of the geography area	General practitioners and ENT specialists in metropolitan France
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2005
Date of last collection (YYYY or MM/YYYY)	2005
Size of the database	
Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	5693
Data	
Database activity	Data collection completed

Type of data collected	Clinical data Declarative data
Clinical data (detail)	Direct physical measures
Declarative data (detail)	Paper self-questionnaire
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services
Care consumption (detail)	Medicines consumption
Procedures	
Data collection method	Patients included were the subject of collection of indirectly personal medical data (medical questionnaire completed by the physician at inclusion and 10 days and 2 months after inclusion) and they also had to complete a self-administered within 10 days following inclusion. Participating physicians were also asked to identify and register all patients with an episode of acute sinusitis (with a maximum of 20 patients).
Participant monitoring	Yes
Details on monitoring of participants	Patients were followed for 2 months with an evaluation point at 10 days and 2 months after diagnosis. These assessment points concerned the evolution of sinusitis and associated care (antibiotics, drainage, other).
Links to administrative sources	No
Promotion and access	
Promotion	
Link to the document	http://tinyurl.com/Pubmed-ABSINTHE
Description	List of publications in Pubmed
Access	
Terms of data access (charter for data provision, format of data, availability delay)	A final study report was submitted to the funder. The final study report and scientific communications (posters, papers, ...) are validated by the study Scientific Committee. Ownership of

	study data is the subject of an agreement between the University of Bordeaux Segalen and the funder. Terms for third-party access to the database are to be defined.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only