

CORINES - Identification of adrenal insufficiency and / or Cushing's syndrome in patients treated with inhaled corticosteroids

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General

Identification

Detailed name	Identification of adrenal insufficiency and / or Cushing's syndrome in patients treated with inhaled corticosteroids
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Sign or acronym	CORINES
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CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL
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General Aspects

Medical area	Endocrinology and metabolism Pediatrics Pneumology
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Health determinants	Iatrogenic Medicine
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Keywords	Adrenal insufficiency, Cushing's syndrome, inhaled corticosteroids, retrospective cohort, pharmacoepidemiology, Department of Pharmacology, Bordeaux
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Scientific investigator(s) (Contact)

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Unit	Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen
Organization	Université Bordeaux
Collaborations	
Funding	
Funding status	Mixed
Details	Laboratoires Merck and Co. (soutien inconditionnel) - Merck and Co. (unconditional support)
Governance of the database	
Sponsor(s) or organisation(s) responsible	Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen
Organisation status	Public
Additional contact	
Main features	
Type of database	
Type of database	Morbidity registers
Additional information regarding sample selection.	Patients were selected by pulmonologists, pediatricians, endocrinologists and emergency physicians in metropolitan France who agreed to participate. They were to identify all patients with adrenal insufficiency and / or Cushing's syndrome under inhaled corticosteroid therapy during the years 2000 to 2005

Database objective

Main objective

The objectives were to identify cases of adrenal insufficiency and / or Cushing's syndrome in patients taking inhaled corticosteroids during the years 2000 to 2005 and describe the circumstances of occurrence of these events in order to propose recommendations to prevent them.

Inclusion criteria

Children or adults treated with inhaled corticosteroids; Having presented symptoms suggestive of adrenal insufficiency and / or Cushing's syndrome during the years 2000 to 2005; First symptoms having appeared during treatment or within 3 months after discontinuation; Patients without adrenal insufficiency and / or Cushing's syndrome known before initiation of treatment with inhaled corticosteroids.

Population type

Age

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)

Population covered

Sick population

Gender

Male
Woman

Geography area

National

Detail of the geography area

Pulmonologists, pediatricians, endocrinologists, emergency physicians in metropolitan France

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)

2005

Date of last collection (YYYY or MM/YYYY)

2006

Size of the database

Size of the database (number of individuals) < 500 individuals

Details of the number of individuals 70 patients éligibles dont 32 patients inclus 70 eligible patients, of whom 32 patients included

Data

Database activity Data collection completed

Type of data collected Clinical data

Clinical data (detail) Direct physical measures

Presence of a biobank No

Health parameters studied
Health event/morbidity
Health event/mortality
Health care consumption and services

Care consumption (detail) Hospitalization
Medicines consumption

Procedures

Data collection method Using a questionnaire the physicians reported all patients meeting the inclusion criteria. For each case, a second questionnaire was sent to the physician to collect all treatments taken by the patient including treatment by systemic corticosteroids, as well as clinical and laboratory findings that could clarify the diagnosis and circumstances of event occurrence.

Participant monitoring No

Links to administrative sources No

Promotion and access

Promotion

Link to the document <http://www.ncbi.nlm.nih.gov/pubmed/18707191>

Access

Terms of data access (charter for data provision, format of data, availability delay) A confidential study report was submitted to the pharmaceutical company. The study report and scientific communications (posters, paper, ...) 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 pharmaceutical company. 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