

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

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Last update : 09/05/2017 | Version : 1 | ID : 2932

General

Identification

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

Sign or acronym CORINES

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation

CNIL

General Aspects

Medical area Endocrinology and metabolism
Pediatrics
Pneumology

Health determinants Iatrogenic
Medicine

Keywords Adrenal insufficiency, Cushing's syndrome, inhaled corticosteroids, retrospective cohort, pharmacoepidemiology, Department of Pharmacology, Bordeaux

Scientific investigator(s) (Contact)

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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 éligible 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