EREMI - Longitudinal study in patients aged 0 to 15 years hospitalised for at least 3 days after receiving at least one drug: risk of adverse drug reactions associated with off-label/unlicensed prescriptions

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General

Identification

Detailed name	Longitudinal study in patients aged 0 to 15 years hospitalised for at least 3 days after receiving at least one drug: risk of adverse drug reactions associated with off-label/unlicensed prescriptions
Sign or acronym	EREMI
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	MMS/MTE/AR1411279

General Aspects

Medical area	Pediatrics
Pathology (details)	Adverse drug reactions
Health determinants	Iatrogenic Medicine
Keywords	drug, ADEs, Adverse drug episodes, adverse effect, market authorisation, prescription, Hospitalisation, MA, child, adolescent

Scientific investigator(s) (Contact)

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Organization	Hospices Civils de Lyon (HCL)

Collaborations

Participation in projects, networks and consortia	Yes
Details	CIC Pédiatrique - Hôpital Femme-Mère-Enfant, Hospices Civils de Lyon (HCL) / CIC pédiatrique - Hôpital Robert Debré, Assistance publique ? Hôpitaux de Paris (AP-HP)

Funding

Funding status	Public
Details	ANSM Financing 2012 - Axis 2: Analysis of off-label drug use

Governance of the database

Sponsor(s) or organisation(s) responsible	Hôpital Femme-Mère-Enfant, Hospices Civils de Lyon (HCL)
Organisation status	Public
Sponsor(s) or organisation(s) responsible	Hôpital Robert Debré, Assistance publique ? Hôpitaux de Paris (AP-HP)
Organisation status	Public
Presence of scientific or steering committees	Yes

Additional contact

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Organization	Hospices Civils de Lyon/UCBL

Main features

Type of database

Type of database	Study databases
Study databases (details)	Cohort study
Database recruitment is carried out by an intermediary	A selection of health institutions and services A population file
Database recruitment is is made on the basis of:	Medication(s) taken
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	Automated prospective extraction of drug administrations from the HCL Hospital Information System / Active and spontaneous detection of adverse drug events

Database objective

Main objective	To compare the probability of occurrence of an adverse drug reaction (ADR) after a licensed

	prescription drug versus the probability of occurrence of an ADR after prescribing a drug off-label or unlicensed in patients aged 0-15 years hospitalized at least 3 days Secondary objectives: ? Compare the proportion of pediatrics inpatients presenting at least one ADR among inpatients with at least one off-labels or unlicensed prescription drug with the proportion of inpatients presenting at least one ADR among inpatients with all licensed prescription drugs ? To describe, in terms of marketing autorisation and indications, the medicinal products prescribed by paediatric age group. ? Identify the factors influencing the risk of developing ADRs after prescribing a drug ? To estimate the seriousness and avoidability of ADRs
Inclusion criteria	Children from 0 to 15 years old [0 ; 15[(including term and preterm newborn infants). Hospitalised for at least 3 days. Receiving at least one medication
Population type	
Age	Newborns (birth to 28 days) Infant (28 days to 2 years) Early childhood (2 to 5 years) Childhood (6 to 13 years) Adolescence (13 to 18 years)
Population covered	Sick population
Pathology	Y40-Y59 - Drugs, medicaments and biological substances causing adverse effects in therapeutic use
Gender	Male Woman
Geography area	Local
Detail of the geography area	Hôpital Femme-Mère-Enfant, Hospices Civils de Lyon (HCL) / Hôpital Robert Debré, Assistance publique ? Hôpitaux de Paris (AP-HP)
Data collection	
Dates	
Date of first collection (YYYY or	2013

MM/YYYY)	
Date of last collection (YYYY or MM/YYYY)	2016
Size of the database	
Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	6227
Data	
Database activity	Current data collection
Type of data collected	Clinical data Declarative data Paraclinical data Biological data Administrative data
Clinical data (detail)	Direct physical measures Medical registration
Details of collected clinical data	Nature and clinical context of ADEs
Declarative data (detail)	Face to face interview Phone interview
Details of collected declarative data	Spontaneous reporting of ADEs by medical teams / Aid to reporting ADEs actively detected by the EREMI team
Biological data (detail)	Creatinine level
Administrative data (detail)	Admission dates, Duration of stay. Extractions from the hospital information system (prescriptions, doses, anthropomorphic and biological data)
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	During hospitalisation
Quality procedure(s) used	Methodology: HCL Paediatric Clinical Investigation Centre; Biostatistics: Biostatistics department of HCL/UMR CNRS 5558; Management of the database: ClinInfo, Lyon
Participant monitoring	Yes
Monitoring procedures	Monitoring by contact with the participant (mail, e-mail, telephone etc.) Monitoring by contact with the referring doctor Monitoring by crossing with a medical-administrative database
Details on monitoring of participants	Duration of monitoring of patients who have had an ADE after discharge: 1 month
Links to administrative sources	Yes
Linked administrative sources (detail)	PMSI

Promotion and access

Promotion

Link to the document	http://adc.bmj.com/content/99/Suppl_2/A62.2.abstract?sid=0943db08-e27a-4da7-bb7a-909ec1a19723; http://www.sciencedirect.com/science/article/pii/S0929693X14719591; http://www.sciencedirect.com/science/article/pii/S0929693X1472130X; http://www.sciencedirect.com/science/article/pii/S0929693X14721311; http://www.sciencedirect.com/science/article/pii/S0929693X14722432
Other information	NCT02852590, protocol available on clinicaltrial.gov (https://clinicaltrials.gov/ct2/show/NCT02852590?term=EREMI&rank=1)

Access

Presence of document that lists variables and coding procedures	Yes
Terms of data access (charter for data provision, format of data, availability delay)	Request from M Behrouz.Kassai (behrouz.kassai-koupai@chu-lyon.fr or Mrs Kim An Nguyen: kim-an.nguyen@chu-lyon.fr
Access to aggregated data	Access on specific project only

Access to individual data	Access on specific project only