MENUI - Cohort of children with isolated nocturnal enuresis : a study of the safety of Minirinmelt in actual prescription

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General

Identification

Detailed name	Cohort of children with isolated nocturnal enuresis : a study of the safety of Minirinmelt in actual prescription
Sign or acronym	MENUI
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CCTIRS (04/06/07), CNIL n°907222 (30/10/07)

General Aspects

Medical area	Endocrinology and metabolism Urology, andrology and nephrology
Others (details)	Isolated nocturnal enuresis
Keywords	desmopressin, Minirin® tablet, Minirinmelt®

Scientific investigator(s) (Contact)

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Collaborations

Funding

Funding status	Private
Details	FERRING S.A.S

Governance of the database	
Sponsor(s) or organisation(s) responsible	Laboratoire FERRING SAS
Organisation status	Private
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 institutions and services
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.	Using the survey base, a preliminary list of 830 doctors (415 pediatricians and 415 general practitioners) will be compiled by random drawing. A letter presenting the survey along with a detailed synopsis of the project and a response coupon will be sent to each doctor on this list. Interested doctors will return the response coupon. If the response rate is insufficient, contacting doctors who have not responded may be considered. If the number of positive responses is too high, a random drawing from the interested doctors will be conducted, complying with the defined proportion of general practitioners and pediatricians. If the number is insufficient, an additional list of doctors will be randomly selected from the survey base described hereinabove, still in compliance with the defined proportion.
Database objective	
Main objective	Show that the two oral forms (tablet and lyophilisate) of desmopressin have a similar safety profile and in particular in terms of frequency of the symptoms of alarms of an intoxication via water, in actual prescription situations, i.e. at general

	practitioners.
Inclusion criteria	Criteria for inclusion: -patient having an isolated nocturnal enuresis, defined by the number of wet nights per week, -patient aged 6 to 18 years, -patient in which the family doctor has decided to prescribe a treatment via desmopressin, or Minirin® tablets or Minirinmelt® lyophilisate. Criteria for non-inclusion: -patient who has already received prior treatment via desmopressin regardless of its form, -patient who has a treatment in progress via desmopressin, -patient participating in a therapeutic study.
Population type	
Age	Childhood (6 to 13 years) Adolescence (13 to 18 years)
Population covered	Sick population
Gender	Male Woman
Geography area	National
Detail of the geography area	Metropolitan France
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2007
Date of last collection (YYYY or MM/YYYY)	2010
Size of the database	
Size of the database (number of individuals)	[500-1000[individuals
Details of the number of individuals	750
Data	
Database activity	Data collection completed

Type of data collected	Clinical data Declarative data Biological data
Clinical data (detail)	Direct physical measures
Declarative data (detail)	Paper self-questionnaire Face to face interview
Biological data (detail)	Natremia collected in the case of an undesirable event if this was requested by the doctor
Presence of a biobank	No
Health parameters studied	Quality of life/health perception Others
Other (detail)	Profile of the patients treated, description of the impact of isolated nocturnal enuresis in patients treated and their families, description of the methods for use of Minirin® tablets and Minirinmelt® lyophilisate

Procedures

Data collection method	Data collected in a paper observation notebook by the doctor using the data from the patient's medical dossier and following the information collected during consultations of the child with his or her parents or legal guardian. Satisfaction of the parents and of the children as well as the information pertaining to the quality of life of the patients (supplemented by the children and by the parents) were collected during the consultations via the filling out of the self-questionnaires at inclusions and when the treatment was stopped for the study.
Participant monitoring	Yes
Details on monitoring of participants	Each patient was followed in the study for a maximum period of 9 months after inclusion. The rate of visits was that of the consultations as normally practiced by the doctors. Following the inclusion the patient was followed for a period referred to as the desmopressin posology adaptation period, until the effective or maximum posology has been reached. This was then followed by a treatment period for the retained posology (1st cure). If the patient benefitted from a 2nd cure of desmopressin, the information was collected by the doctor until the end of the treatment. At each consultation, the doctor checked if the patient had any undesirable events. If so, the doctor filled out

	the undesirable event collection form and then faxed it to the pharmacovigilance department of Ferring S.A.S. Each serious or non-serious undesirable event was follow-up until its end.
Links to administrative sources	No
Promotion and access	
Promotion **Access**	
Terms of data access (charter for data provision, format of data, availability delay)	Methods for accessing the results: study report, submitted congress abstract, publication: manuscript currently being drafted. Methods for accessing the database are currently being defined.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only