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

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Général

Identification

Nom détaillé	Cohort of children with isolated nocturnal enuresis : a study of the safety of Minirinmelt in actual prescription
Sigle ou acronyme	MENUI
Numéro d'enregistrement (ID-RCB ou EUDRACT, CNIL, CPP, etc.)	CCTIRS (04/06/07), CNIL n°907222 (30/10/07)

Thématiques générales

Domaine médical	Endocrinology and metabolism Urology, andrology and nephrology
Autres, précisions	Isolated nocturnal enuresis
Mots-clés	desmopressin, Minirin® tablet, Minirinmelt®

Responsable(s) scientifique(s)

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Collaborations

Financements

Financements	Private
Précisions	FERRING S.A.S

Gouvernance de la base de données

Organisation(s) responsable(s) ou promoteur	Laboratoire FERRING SAS
Statut de l'organisation	Secteur Privé

Contact(s) supplémentaire(s)

Caractéristiques

Type de base de données

Type de base de données	Study databases
Base de données issues d'enquêtes, précisions	Longitudinal study (except cohorts)
Origine du recrutement des participants	A selection of health institutions and services
Critère de sélection des participants	Medication(s) taken
Le recrutement dans la base de données s'effectue dans le cadre d'une étude interventionnelle	No
Informations complémentaires concernant la constitution de l'échantillon	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.

Objectif de la base de données

Objectif principal	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.
Critères d'inclusion	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.
Type de population	
Age	Childhood (6 to 13 years) Adolescence (13 to 18 years)
Population concernée	Sick population
Sexe	Male Woman
Champ géographique	National
Détail du champ géographique	Metropolitan France
Collecte	
Dates	
Année du premier recueil	2007
Année du dernier recueil	2010
Taille de la base de données	
Taille de la base de données (en nombre d'individus)	[500-1000[individuals
Détail du nombre d'individus	750
Données	
Activité de la base	Data collection completed
Type de données recueillies	Clinical data Declarative data Biological data

Données cliniques, précisions	Direct physical measures
Données déclaratives, précisions	Paper self-questionnaire Face to face interview
Données biologiques, précisions	Natremia collected in the case of an undesirable event if this was requested by the doctor
Existence d'une biothèque	No
Paramètres de santé étudiés	Quality of life/health perception Others
Autres, précisions	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

Modalités

Mode de recueil des données	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.
Suivi des participants	Yes
Détail du suivi	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.
Appariement avec des sources administratives	No
Valorisation et accès	
Valorisation et accès **Accès**	
Charte d'accès aux données (convention de mise à disposition, format de données et délais de mise à disposition)	Methods for accessing the results: study report, submitted congress abstract, publication: manuscript currently being drafted. Methods for accessing the database are currently being defined.
Accès aux données agrégées	Access on specific project only
Accès aux données individuelles	Access on specific project only