EULEV - Effectiveness and Use of Levetiracetam in Real Life

Responsable(s) :Fourrier-Reglat Annie, Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen
Moore Nicholas, Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen

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Général

Identification

Nom détaillé	Effectiveness and Use of Levetiracetam in Real Life
Sigle ou acronyme	EULEV
Numéro d'enregistrement (ID-RCB ou EUDRACT, CNIL, CPP, etc.)	CCTIRS 04.198, CNIL 904498

Thématiques générales

Domaine médical	Neurology Psychology and psychiatry
Déterminants de santé	Iatrogenic Medicine
Mots-clés	Levetiracetam, prescribing patterns, effectiveness, pharmacoepidemiology, cohort, Department of Pharmacology, Bordeaux

Responsable(s) scientifique(s)

Nom du responsable	Fourrier-Reglat
Prénom	Annie
Adresse	Bât du Tondu - Case 41 - 146, Rue Léo Saignat - 33076 BORDEAUX Cedex
Téléphone	+ 33 (0)5 57 57 46 75
Email	annie.fourrier@pharmaco.u-bordeaux2.fr
Laboratoire	Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen
Organisme	Université Bordeaux
Nom du responsable	Moore

Prénom	Nicholas
Adresse	Bât du Tondu - Case 41 - 146, Rue Léo Saignat - 33076 BORDEAUX Cedex
Téléphone	+ 33 (0)5 57 57 46 75
Email	nicholas.moore@pharmaco.u-bordeaux2.fr
Laboratoire	Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen
Organisme	Université Bordeaux

Collaborations

Financements

Financements	Mixed
Précisions	Laboratoire UCB Pharma (soutien inconditionnel) - UCB Pharma (unconditional support) - Inserm

Gouvernance de la base de données

Organisation(s) responsable(s) ou promoteur	INSERM
Statut de l'organisation	Secteur Public

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	Two parallel and complementary studies have been implemented. An observational study was conducted among a sample of hospital and non-hospital neurologists who were to retrospectively include over two periods 1000 patients who had received a first prescription of levetiracetam (between 1 January and 31 August 2005, or between January 1 and August 31, 2006 for the second period). For each inclusion period, all neurologists registered in the "Cegedim" database were invited by post to participate in the study.In parallel, a study based on the EPIB sample from the SNIIRAM database was performed using two extractions of anonymised data of patients who had at least one reimbursement of levetiracetam between 1 July 2004 and 31 August 2005 for the first extraction and between 1 July 2005 and 31 August 2006 for the second.The study based on the EPIB sample allowed the verification of the field study sample validity and to collect information independently of the field study.

Objectif de la base de données

Objectif principal	The objectives of this study were to describe patients initiating treatment with levetiracetam, the prescribing patterns, and to evaluate the effectiveness of levetiracetam in a real-life situation in terms of treatment retention over one year.
Critères d'inclusion	Patients who initiated treatment with levetiracetam between 01/01/2005 and 31/08/2005 or between 01/01/2006 and 31/08/2006 (irrespective of whether or not treatment was continued), and having never previously been treated with levetiracetam; patient agreeing to participate; patient can be followed over the next 12 months; Patient not participating in a clinical trial (Huriet-Sérusclat).

Type de population

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) 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 concernée	Sick population
Sexe	Male Woman
Champ géographique	National
Détail du champ géographique	Hospital and non-hospital neurologists in metropolitan France

Collecte

Dates

Année du premier recueil	2006
Année du dernier recueil	2008

Taille de la base de données

Taille de la base de données (en nombre d'individus)	[500-1000[individuals
Détail du nombre d'individus	858

Données

Activité de la base	Data collection completed
Type de données recueillies	Clinical data
Données cliniques, précisions	Direct physical measures
Existence d'une biothèque	No
Paramètres de santé étudiés	Health event/morbidity Health event/mortality Health care consumption and services
Consommation de soins, précisions	Hospitalization Medical/paramedical consultation Medicines consumption

Modalités

Mode de recueil des données	Included patients were the subject of collection of indirectly personal medical data (patient questionnaire completed by the neurologist) at inclusion, at each follow-up visit, and at one year of follow-up or in case of discontinuation of levetiracetam data will be collected for all patients.

Suivi des participants	Yes
Détail du suivi	Levetiracetam-treated patients were followed for a period of one year (from date of levetiracetam initiation).
Appariement avec des sources administratives	No

Valorisation et accès

Valorisation et accès

Lien vers le document	http://www.ncbi.nlm.nih.gov/pubmed?term=eulev%20NOT%20eulevp&cmd=correctspelling
Description	List of publications in Pubmed

Accès

Charte d'accès aux données (convention de mise à disposition, format de données et délais de mise à disposition)	A final study report was submitted to the funder. The final study report and scientific communications (posters, articles, ...) 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 funder. Terms for third-party access to the database are to be defined.
Accès aux données agrégées	Access on specific project only
Accès aux données individuelles	Access on specific project only