PSOBIOTEQ - Multicentric Cohort of Patients Receiving Systemic Treatment (Conventional or Biotherapy) for Moderate to Severe Cutaneous Psoriasis

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Général

Identification

Nom détaillé	Multicentric Cohort of Patients Receiving Systemic Treatment (Conventional or Biotherapy) for Moderate to Severe Cutaneous Psoriasis
Sigle ou acronyme	PSOBIOTEQ
Numéro d'enregistrement (ID-RCB ou EUDRACT, CNIL, CPP, etc.)	CNIL: 911408

Thématiques générales

Domaine médical	Cancer research Dermatology, venereology
Déterminants de santé	Medicine
Mots-clés	systemic conventional treatment, methotrexate, cyclosporine, health safety, real life, skin cancer, carcinoma, usage, biotherapy, infliximab, adalimumab, etanercept, ustekinumab, pharmacoepidemiology, exposure, melanoma

Responsable(s) scientifique(s)

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Organisme	AP-HP

Collaborations

Participation à des projets, des réseaux, des consortiums	Yes
Précisions	The PSOBIOTEQ meets the objective of the European PSONET project to develop standardised procedures for the sharing and analysis of national data registers for the long-term monitoring of the efficacy and safety of systemic psoriasis treatment.

Financements

Financements	Mixed
Précisions	Assistance Publique - Hôpitaux de Paris (Paris Public Hospital System), Ministry of Health (PHRC 2009). Agence Nationale de Sécurité du Médicament et des produits de santé (ANSM) [French National Agency for Medicine and Health Product Safety]. Janssen LP, Pfizer, Abbott, Merck Sharp and Dohme Corp laboratories.

Gouvernance de la base de données

Organisation(s) responsable(s) ou promoteur	AP-HP
Statut de l'organisation	Secteur Public
Organisation(s) responsable(s) ou promoteur	Société Française de Dermatologie

Statut de l'organisation	Secteur Public
Organisation(s) responsable(s) ou promoteur	ABBVIE France
Statut de l'organisation	Secteur Privé
Organisation(s) responsable(s) ou promoteur	JANSSEN-CILAG
Statut de l'organisation	Secteur Privé
Organisation(s) responsable(s) ou promoteur	PFIZER
Statut de l'organisation	Secteur Privé
Organisation(s) responsable(s) ou promoteur	MSD FRANCE
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	Cohort study
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	- Unexposed group: 1,200 patients - exposed group: - 1,200 biotherapy-naive patients - 1,436 non-biotherapy-naive patients with at least 323 patients treated with each biotherapy.

Objectif de la base de données

Objectif principal	PSOBIOTEQ is a national multicentric prospective

	cohort of cutaneous psoriasis patients receiving systemic treatment (biotherapy or conventional treatment) for moderate to severe cutaneous psoriasis. PSOBIOTEQ is the result of merging two studies that share the same study population but address different objectives: PSOBIO, developed by academic dermatologists and epidemiologists focusing on safety issues, and Pso-TEQ, developed by industrial teams at the request of the French Transparency Commission (Haute Autorité de Santé) that focuses on usage issues. The exposure of interest is the biological therapy exposure: Infliximab, Adalimumab, Etanercept and Ustekinumab. The general objective of PSOBIO is to assess the safety and efficacy of biotherapy in the treatment of cutaneous psoriasis "in real life" compared with conventional systemic therapy. However, Pso-TEQ has a descriptive objective concerning the usage methods of biological therapies "in real life" and the long-term benefits.
Critères d'inclusion	Inclusion criteria: - Patients aged 18 or over; - Attending or hospitalised in services participating in the study; - Has been informed of the research objectives and outcome and has signed an informed consent form to participate; - Cutaneous psoriasis (clinical diagnosis); - Justifying the prescription of major systemic therapy (Methotrexate or Cyclosporine or biotherapy) and belongs to one of the following 3 groups: - Patients beginning biotherapy (Infliximab, Adalimumab, Etanercept, Ustekinumab and other biotherapy entering the market) AND who have not been previously exposed; - Patients beginning biotherapy AND who have been already exposed. - Patients exposed to major conventional systemic treatment (excluding biotherapy) for at least 3 months (Methotrexate or Cyclosporine) AND for which no biotherapy treatment is planned within the next 6 months AND are naive to all biotherapy. Exclusion criteria: - Patients for whom cutaneous psoriasis is not the main reason for systemic treatment (biotherapy or

	conventional treatment); treatment justified by psoriatic arthritis, concomitant Crohn's disease, etc. - Patients unable to comply with the cohort monitoring (unreachable by phone, unable to complete the self -administered questionnaire) or whose follow-up is expected to be difficult.
Type de population	
Age	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	Metropolitan France
Collecte	
Dates	
Année du premier recueil	07/2012
Année du dernier recueil	07/2020
Taille de la base de données	
Taille de la base de données (en nombre d'individus)	[1000-10 000[individuals
Détail du nombre d'individus	2,636
Données	
Activité de la base	Current data collection
Type de données recueillies	Clinical data Declarative data Paraclinical data Biological data
Données cliniques, précisions	Direct physical measures Medical registration
Détail des données cliniques	--

recueillies	
Données déclaratives, précisions	Paper self-questionnaire Phone interview
Détail des données déclaratives recueillies	SQ completed by patients at each study visit and telephone contact between follow-up visits.
Données paracliniques, précisions	--
Données biologiques, précisions	--
Existence d'une biothèque	No
Paramètres de santé étudiés	Health event/morbidity Health event/mortality Health care consumption and services Quality of life/health perception
Consommation de soins, précisions	Medicines consumption

Modalités

Mode de recueil des données	Collection of clinical and paraclinical data within the cohort will be carried out using a CleanWEB Electronic Case Report Form. An adjudication committee shall validate the potential SAEs and significant medical effects presented to them. The events requiring adjudication will be listed by the Scientific Committee for the study. Events to be adjudicated will be sent to experts through anonymised data transfer by CRA under the coordination of the project head. Adjudication will be applied to treatment received (biotherapy or not), based on clinical history and to possible photographs and additional adapted tests.
Nomenclatures employées	MeDRA
Suivi des participants	Yes
Détail du suivi	Follow-up every 6 months for a minimum of 5 years and a maximum of 8 years. A self-administered questionnaire was completed by the patient at each visit and follow-up by telephone is in place for the prompt notification of an event or change in treatment and to ensure continuous monitoring.
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)	Data belongs to AP-HP and cannot be used or sent to a third party without prior consent. Access to data is by request to the Psobioteq project scientific committee; Access shall also be subject to a partnership contract signed between AP-HP and the legal representative of the requesting team specifying the terms and conditions of data provision. Every laboratory participating in the Psobioteq study will have access to data involving their product. Psonet study variables (European study) will be sent to the European registry according to the terms outlined in a specific document.
Accès aux données agrégées	Access on specific project only
Accès aux données individuelles	Access on specific project only