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

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General

Identification

Detailed name	Multicentric Cohort of Patients Receiving Systemic Treatment (Conventional or Biotherapy) for Moderate to Severe Cutaneous Psoriasis
Sign or acronym	PSOBIOTEQ
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL: 911408

General Aspects

Medical area	Cancer research Dermatology, venereology
Health determinants	Medicine
Keywords	systemic conventional treatment, methotrexate, cyclosporine, health safety, real life, skin cancer, carcinoma, usage, biotherapy, infliximab, adalimumab, etanercept, ustekinumab, pharmacoepidemiology, exposure, melanoma

Scientific investigator(s) (Contact)

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Organization	AP-HP

Collaborations

Participation in projects, networks and consortia	Yes
Details	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.

Funding

Funding status	Mixed
Details	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.

Governance of the database

Sponsor(s) or organisation(s) responsible	AP-HP
Organisation status	Public
Sponsor(s) or organisation(s)	Société Française de Dermatologie

responsible	
Organisation status	Public
Sponsor(s) or organisation(s) responsible	ABBVIE France
Organisation status	Private
Sponsor(s) or organisation(s) responsible	JANSSEN-CILAG
Organisation status	Private
Sponsor(s) or organisation(s) responsible	PFIZER
Organisation status	Private
Sponsor(s) or organisation(s) responsible	MSD FRANCE
Organisation status	Private

Additional contact

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
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.	- 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.

Database objective

Main objective	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.
Inclusion criteria	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.
Population type	
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 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)	07/2012
Date of last collection (YYYY or MM/YYYY)	07/2020
Size of the database	
Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	2,636
Data	
Database activity	Current data collection
Type of data collected	Clinical data Declarative data Paraclinical data Biological data
Clinical data (detail)	Direct physical measures Medical registration

Details of collected clinical data	--
Declarative data (detail)	Paper self-questionnaire Phone interview
Details of collected declarative data	SQ completed by patients at each study visit and telephone contact between follow-up visits.
Paraclinical data (detail)	--
Biological data (detail)	--
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services Quality of life/health perception
Care consumption (detail)	Medicines consumption

Procedures

Data collection method	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.
Classifications used	MeDRA
Participant monitoring	Yes
Details on monitoring of participants	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.
Links to administrative sources	No

Promotion and access

Promotion Access	
Terms of data access (charter for data provision, format of data, availability delay)	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.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only