Biological drugs in patients with psoriasis: a drug-utilization study using Tuscan administrative data banks

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Study Ongoing

Administrative details

EU PAS number

EUPAS45365

Study ID

45366

DARWIN EU® study

No

Study countries

☐ Italy

Study description

This is a drug utilization study of biological drugs for psoriasis, in the Tuscany region of Italy, from 2011 to 2016.

Study status

Ongoing

Research institutions and networks

Institutions

University of Pisa

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Ersilia Lucenteforte

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 06/07/2020

Actual: 06/07/2020

Study start date
Planned: 01/05/2020

Actual: 01/05/2020

Data analysis start date
Planned: 01/06/2020

Actual: 01/06/2020

Date of final study report
Planned: 01/03/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

University

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

To evaluate the utilization of biologic drugs for psoriasis in the population of Tuscany using real-world data

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L04AB04) adalimumab

adalimumab

(L04AB01) etanercept

etanercept

(L04AB02) infliximab

infliximab

(L04AC10) secukinumab

secukinumab

(L04AC05) ustekinumab

ustekinumab

Medical condition to be studied

Psoriasis

Population studied

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

2000

Study design details

Outcomes

- Identification of longitudinal patterns of adherence behavior through trajectory models - Investigation of switches of PSObio drugs

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Data analysis plan

Treatment trajectories will be identified through two different methodological approaches: the first one is purely descriptive and it is based on the cluster analysis, whereas the second one is the group-based trajectory modeling (GBTM). Furthermore, patterns of switches will be identified using the state sequence analysis.

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Other

Data sources (types), other

Disease-specific exemptions from copayment

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No