Italian healthcare resource consumptions and direct costs of adults with atopic dermatitis before and after dupilumab treatment

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Study Finalised

Administrative details

EU PAS number

EUPAS1000000328

Study ID

1000000328

DARWIN EU® study

No

Study countries

☐ Italy

Study description

Background: Atopic dermatitis (AD) is a heterogeneous disease, associated with comorbidities, and high healthcare consumptions and costs. This study assessed the burden before and after treatment with dupilumab in adults with severe AD from 2018 to 2020, from the perspective of the Italian National Health Service (SSN).
Methods: From Fondazione Ricerca e Salute's administrative healthcare database (~5 million inhabitants/year), adults treated with dupilumab from 09/01/2018 to 31/12/2020 (index date) and a five-year lookback were identified. Age, sex and comorbidities at baseline, concomitant drugs, overnight hospitalizations, outpatient specialist services and direct costs charged to the SSN one year before/after index date were assessed.
Results: Of 337 adults treated with dupilumab (5.8x100,000 adult inhabitants/2019; 8.0x100,000/2020; 55% males; mean age 43±19), 68% (228/337) had ≥12-month follow-up available. Asthma was a common comorbidity (23% patients). Rates of patients treated with nearly all concomitant AD-related therapies reduced from 12 months before to 12 months after dupilumab treatment: antibacterials (from 59% to 50%), systemic corticosteroids (55% to 29%), antihistamines (54% to 38%) and cyclosporine (52% to 7%). A similar trend was observed among patients with asthma as comorbidity. Within 12 months before/after dupilumab, patients hospitalized halved from 14% to 7%, and patients receiving outpatient specialist care reduced from 72% to 65%. Annual mean direct total costs per patient treated with dupilumab charged to the SSN, net of dupilumab cost, were €1384 and €773, before and after dupilumab dispensation, respectively.
Conclusions: Before dupilumab, observed patients had higher healthcare resource consumptions and direct SSN costs than after dupilumab.

Study status

Finalised

Research institutions and networks

Institutions

Fondazione ReS (Ricerca e Salute), CINECA partner

Italy

First published: 05/07/2017

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Institution | Not-for-profit | ENCePP partner

Contact details

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 30/06/2022

Study start date

Actual: 30/07/2022

Date of final study report
Actual: 30/12/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

This article is funded by Sanofi.

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 list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Healthcare resource utilisation

Data collection methods:

Secondary use of data

Study design:

Adults treated with dupilumab from 09/01/2018 to 31/12/2020 (index date) were identified. Age, sex and comorbidities during a five-year lookback period, concomitant drugs, overnight hospitalization, outpatient specialist services and direct costs charged to the SSN one year before/after index date

Main study objective:

This study assessed the burden before and after treatment with dupilumab in adults with severe AD from 2018 to 2020, from the perspective of the Italian National Health Service (SSN).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

DUPIXENT

Study drug International non-proprietary name (INN) or common name

DUPILUMAB

Anatomical Therapeutic Chemical (ATC) code

(D11AH05) dupilumab

dupilumab

Medical condition to be studied

Dermatitis atopic

Additional medical condition(s)

Severe atopic dermatitis

Population studied

Short description of the study population

Adults with at least one supply of dupilumab (ATC code D11AH05) from 1st September 2018 to 1st December 2020, with a five-year lookback period and until 31st December 2020. Given that, in Italy, the reimbursement of dupilumab for adult patients was granted to severe AD (eligibility criteria: EASI score ≥24 who have failed or are inadvisable for the treatment with cyclosporine) until the beginning of December 2020, the dispensation of dupilumab during the accrual period, from 1st September 2018 to 1st December 2020, was used as the specific inclusion criterion to identify patients with AD (namely, the only indication reimbursed at that time).

Age groups

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

337

Study design details

Setting

Inpatient and local outpatient

Summary results

Of 337 adults treated with dupilumab (5.8x100,000 adult inhabitants/2019; 8.0x100,000/2020; 55% males; mean age 43±19), 68% (228/337) had ≥12-month follow-up available. Asthma was a common comorbidity (23% patients). Rates of patients treated with nearly all concomitant AD-related therapies reduced from 12 months before to 12 months after dupilumab treatment: antibacterials (from 59% to 50%), systemic corticosteroids (55% to 29%), antihistamines (54% to 38%) and cyclosporine (52% to 7%). A similar trend was observed among patients with asthma as comorbidity. Within 12 months before/after dupilumab, patients hospitalized halved from 14% to 7%, and patients receiving outpatient specialist care reduced from 72% to 65%. Annual mean direct total costs per patient treated with dupilumab charged to the SSN,

net of dupilumab cost, were €1384 and €773, before and after dupilumab dispensation, respectively.

Documents

Study publications

Italian healthcare resource consumptions and direct costs of adults with atopic…

Data management

Data sources

Data source(s)

Database of Fondazione ReS

Data sources (types)

Administrative healthcare records (e.g., claims)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes