Impact of Body Mass Index and Obesity on Clinical Response to Systemic Treatment for Psoriasis (Evidence from the Psocare Project)

First published: 13/10/2010

Last updated: 29/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS1620

Study ID

16746

DARWIN EU® study

No

Study countries

Italy

Study description

Objective: Our aim was to assess the role of the body mass index (BMI) in the clinical response to systemic treatment for psoriasis. Methods: A nationwide cohort study of patients receiving a new systemic treatment for plaque psoriasis at reference centres in Italy was conducted. Information was gathered through a web-based electronic form. Patients being maintained on the same medication and with data available at 8 and 16 weeks by March 31, 2007, were eligible. The outcome was a reduction in the Psoriasis Area Severity Index (PASI) of at least 75% at follow-up compared to baseline (PASI-75). Results: Out of 8,072 patients enrolled, 2,368 were eligible and analysable at 8 weeks and 2,042 at 16 weeks. PASI-75 was achieved by 819 patients (34.5%) at 8 weeks and1,034 (50.6%) at 16 weeks. The proportion steadily decreased with increased values of BMI. Compared to normal weight (BMI = 20–24) the adjusted odds ratio for achieving PASI-75 in obese patients was 0.73 (95% CI = 0.58–0.93) at 8 weeks and 0.62 (95% CI = 0.49–0.79) at 16 weeks. The impact of the BMI did not show remarkable variations according to the drug prescribed at entry. Conclusion: The BMI affects the early clinical response to systemic treatment for psoriasis.

Study status

Finalised

Research institutions and networks

Institutions

Centro Studi GISED

Italy

First published: 17/04/2012

Last updated: 20/08/2024

Institution | Not-for-profit

Multiple centres: 147 centres are involved in the study

Psocare, Italy

Networks

Psocare

Contact details

Study institution contact

Luigi Naldi luigi.naldi@gised.it

Study contact

luigi.naldi@gised.it

Primary lead investigator

Luigi Naldi

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/06/2005

Actual: 24/04/2012

Study start date
Planned: 01/09/2005

Actual: 02/10/2012

Date of final study report
Planned: 31/03/2007

Actual: 05/11/2013

Sources of funding

- Other

More details on funding

Agenzia Italiana del Farmaco

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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

-to assess the prevalence of exposure to topical NSAIDs in a sample of hospital controls selected as in case-control studies-to develop strict diagnostic criteria for severe photosensitivity-to estimate the incidence of severe photosensitivity leading to hospitalization in selected sampling areas.

Study Design

Non-interventional study design

Case-control

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(M01A) ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS

ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS

(M01AE03) ketoprofen

ketoprofen

Medical condition to be studied

Photosensitivity reaction

Population studied

Short description of the study population

Patients receiving a new systemic treatment for plaque psoriasis at reference centres in Italy.

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)

Special population of interest

Other

Special population of interest, other

Plaque psoriasis patients

Estimated number of subjects

900

Study design details

Outcomes

-the estimate of prevalence of exposure to topical ketoprofen in the general population. A secondary outcome will be the prevalence of exposure to other topical NSAIDs -The definition of a standard operative procedure for the identification and diagnosis of photosensitivity reactions-The estimate of the incidence of photosensitivity reactions in selected European areas

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Data analysis plan

Row and age-standardized prevalence rates together with their 95% confidence intervals (CI) will be calculated for NSAIDs exposure as well as for other variables of interest. Stratification by gender and country will be used for general descriptive statistics as well as for exposure rates. Differences among categories will be tested with Pearson’s chi-squared test or Fisher’s exact test for nominal variables and by Mann-Whitney U test for continuous variables. To estimate possible selection biases in the collection of the sample, a comparison of general characteristics of individuals undergoing the interview and, in particular, their exposure rates to topical NSAIDs, with the expected distribution based on demographic and general sales data obtained from individual areas will be made. Whenever it will be possible risk estimate for exposure will be derived from odds ratio calculation. Multiple logistic regressions will be used to adjust risk estimates for potential confounders.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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

Unknown