A Cross-sectional and retrospective chart review study for assessing psoRiasis severitY by absolute PASI score in moderaTe to severe psoriatic pAtients routineLy treated with systemic treatment in Bulgaria, Estonia, Hungary, Latvia, Lithuania, Romania and Russia - The CRYSTAL Study

First published: 31/08/2020

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS36459

Study ID

45286

DARWIN EU® study

No

Study countries

Bulgaria

Estonia

Hungary

Latvia

Lithuania

Romania

Russian Federation

Study description

The main research question is what is the absolute PASI score and associated HRQoL of moderate to severe psoriatic patients routinely managed with systemic treatment for at least 24 weeks under real-world conditions of daily clinical practice in Bulgaria, Estonia, Hungary, Latvia, Lithuania, Romania and Russia.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 50 centres are involved in the study

Contact details

Study institution contact

Clinical Trial Disclosure AbbVie CT.Disclosures@abbvie.com

Study contact

CT.Disclosures@abbvie.com

Primary lead investigator

Clinical Trial Disclosure AbbVie

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 28/02/2020

Actual: 28/02/2020

Study start date

Planned: 01/09/2020

Actual: 01/09/2020

Date of final study report

Planned: 11/02/2022

Actual: 02/11/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AbbVie

Study protocol

CRYSTAL (H20-249) protocol synopsis_05Jun2020.pdf (111.19 KB)

CRYSTAL (H20-249) protocol with admin change 02_05Jun2020_Redacted.pdf (1.53 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

H20-249

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Primary data collection

Main study objective:

To characterize the current disease severity, by assessing the absolute Psoriasis Area Severity Index (PASI) score of patients with moderate to severe psoriasis that have been under continuous systemic treatment (either as monotherapy or as combination regimens) for at least 24 weeks.

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Chart review study

Study drug and medical condition

Medical condition to be studied

Psoriasis

Population studied

Short description of the study population

Inclusion Criteria

• Male or female outpatients aged between 18 and 75 years old (inclusive) at the time of informed consent signature.

• Confirmed diagnosis of moderate to severe chronic plaque-type psoriasis diagnosed by a specialist at the time of initiating the current systemic treatment for psoriasis.

• Patients currently treated with any approved systemic treatment for psoriasis, either as monotherapy or combination therapy, continuously for at least 24 weeks. • Patients with available absolute PASI score at the start of their current systemic treatment, and for whom the study physician plans to assess their absolute PASI score at the study visit as per his/her routine practice.

• Patients able to understand and communicate with the investigator and comply with the requirements of the study.

• Patients must be willing and able to read, understand and complete the provided patient questionnaires.

• Patients must provide written informed consent form (ICF) for collecting and analyzing their medical data pertinent to the objectives of this study.

Exclusion Criteria

• Patients not willing to participate in the study.

• Patients who are currently receiving treatment with any investigational drug/device/intervention or have received any investigational product within 1

month or 5 half-lives of the investigational agent (whichever is longer) prior to enrollment.

Age groups

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

Special population of interest

Immunocompromised

Estimated number of subjects

690

Study design details

Outcomes

Mean absolute PASI score of the overall study population at enrollment. 1.To assess the absolute PASI <=1/<=3/<=5 response rates at enrollment, and to capture the duration of the current absolute PASI score, overall and by current systemic treatment option 2.To assess the absolute PASI >5 and >8 rates at enrollment, overall and by current systemic treatment option 3.To describe patient treatment history 4.To describe current systemic treatment for psoriasis

Data analysis plan

Statistical analysis will be performed using SAS® statistical analysis software. Categorical variables will be presented as absolute and relative frequencies. For continuous variables, summary statistics will be tabulated. Correlations between continuous variables (i.e. HRQoL and absolute PASI score at enrollment) will be examined using Pearson’s or Spearman’s correlation

coefficient, as applicable. The effect of factors of interest on the primary outcome variable (i.e. absolute PASI score at enrollment) will be assessed by general linear models i.e. linear regression model, Analysis of Variance (ANOVA), Analysis of Covariance (ANCOVA) using both the univariable and multivariable approach. All statistical analyses will be performed in the set of all eligible patients with available data.

Documents

Study results

H20-249_CRYSTAL_v1_Abstract_2021.pdf (901.99 KB)

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

Web Based Data Capture (WBDC) system.

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