Prospective, observational, noninterventional, multicenter real-world evidence study on effectiveness and safety of treatment of patients with moderate to severe Chronic Hand Eczema with delgocitinib cream (20mg/g) (REACHED)

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Administrative details

EU PAS number

EUPAS1000000731

Study ID

1000000731

DARWIN EU® study

No

Study countries

Study status

Ongoing

Research institutions and networks

Institutions

Dermatologie Potsdam MVZ

Contact details

Study institution contact

Khusru Asadullah khusru.asadullah@charite.de

Study contact

khusru.asadullah@charite.de

Primary lead investigator

Khusru Asadullah

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 09/12/2024

Study start date

Actual: 06/06/2025

Date of final study report

Planned: 31/03/2028

Sources of funding

• Pharmaceutical company and other private sector

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

NIS-DELGO-2396

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Other

If 'other', further details on the scope of the study

Efficacy and safety study with no comparator

Data collection methods:

Primary data collection

Study design:

A single-country, non-interventional, multicenter, non-comparative, prospective, 52-week observational cohort study based on primary data collection.

Main study objective:

The research question is to describe the effectiveness, safety profile, and usage of delgocitinib cream in routine clinical practice in Germany over a 52-week observation period.

Study drug and medical condition

Name of medicine

ANZUPGO

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

Anatomical Therapeutic Chemical (ATC) code

(D11AH11) delgocitinib delgocitinib

Additional medical condition(s)

Chronic Hand Eczema (CHE)

Population studied

Short description of the study population

Patients with moderate to severe CHE eligible for treatment with delgocitinib cream as per physicians discretion and for whom the decision for treatment with delgocitinib cream was made prior to inclusion.

Age groups

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Elderly (≥ 65 years)

Estimated number of subjects

500

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)

Electronic healthcare records (EHR)

Patient surveys

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