Register project for the Characterization and Treatment of moderate to severe atopic Hand and Foot eczema (ReaCT aH&FE)

First published: 02/09/2025

Last updated: 02/09/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000727

Study ID

1000000727

DARWIN EU® study

No

Study countries

Germany

Study description

Prospective, national, multicenter, academic, clinical registry for patients with moderate-to-severe atopic hand- and foot eczema (aH&FE) (non-interventional registry study)

Study status

Ongoing

Research institutions and networks

Institutions

TU Dresden, Department of Medicine

Germany

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution

Contact details

Study institution contact

Sigrid Mueller sigrid.mueller@ukdd.de

Study contact

sigrid.mueller@ukdd.de

Primary lead investigator

Andrea Bauer 0000-0002-4411-3088

Primary lead investigator

ORCID number:

0000-0002-4411-3088

Study timelines

Date when funding contract was signed
Actual: 19/02/2025

Study start date
Actual: 22/08/2025

Date of final study report
Planned: 27/06/2029

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi-Aventis Deutschland GmbH

Study protocol

ReaCT_study_protocol_v2.0_20250708_final.pdf (911.27 KB)

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

Study type:

Non-interventional study

Data collection methods:

Primary data collection

Study design:

prospective, multicenter, non-interventional, clinical, academic, national registry for adult patients suffering of moderate to severe atopic hand and/or foot eczema

standardized visit documentation takes place at routine care visits every 3 to 6 months in outpatient care

Main study objective:

Primary objectives

- To establish a national, science-led clinical registry and research network
- To characterize medical care and pharmaceutical therapies in adults suffering from moderate-to-severe aH&FE
- To investigate the perspective of the patient (quality of life, POEM, itch, pain, sleep disturbance, ability to work, treatment satisfaction)
- To investigate the real-world efficacy of biologicals vs. conventional therapies, tolerability and safety of conventional and biologic treatment modalities, sequence of treatments, drug survival and change of treatments in patients suffering from moderate to severe aH&FE
- To register adverse events of systemic treatments in moderate to severe aH&FE

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

registry based cohort study

Study drug and medical condition

Medical condition to be studied

Dermatitis

Dermatitis atopic

Hand dermatitis

Eczema

Additional medical condition(s)

atopic foot eczema

Population studied

Short description of the study population

adult patients with moderate to severe atopic hand and/or foot eczema, who provide informed consent

Inclusion criteria:
- 18-100 years of age
- Consultation at one of the (German) study sites
- Confirmed diagnosis of aH&FE
- At least moderate AD of either hands or feet - assessed with Hand Eczema Severity Index (HECSI) ≥ 17 and/or Foot Eczema Severity Index (FECSI, analogous to HECSI)
- Indication of anti-inflammatory systemic therapy for aH&FE, or anti-inflammatory systemic therapy for aH&FE conducted within the past 24 months

Exclusion critieria:
- Insufficient German skills for completion of study questionnaires
- EASI ≥ 16

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

500

Study design details

Setting

- Recruitment sites: dermatological hospitals, outpatient dermatologists with focus on aH&FE/ allergology/ atopic dermatitis in Germany, after site initiation

- No study related intervention will be performed.
- Included patients will be prospectively followed. A maximum duration of follow-up is not intended.
- Standardized study visits are performed during routine care visits to prospectively document patient characteristics, clinical data, patient-reported outcomes, physicians’ reasons for treatment decisions, and satisfaction with treatment, about every 3 to 6 month, additional visits possible 4-weeks after start of new therapy.

Outcomes

All results will be reported in aggregated form so that no conclusions can be drawn about individual patients.

Primary Endpoints:
In analogy to the recommendations of the HOME initiative, we consider changes in the following primary endpoints for real-world efficacy of applied therapies:
- Objective severity of clinical signs, in ReaCT measured with HECSI-50, HECSI-75, and HECSI-90 six months after treatment was first prescribed (analogue analyses concerning FE)
- Patient-reported symptoms measured with POEM six months after treatment was first prescribed
- Disease control over time measured with RECAP six months after treatment was first prescribed
- Quality of life measured with HEIS six months after treatment was first prescribed

Another primary endpoint is the safety of applied treatments at each visit.

Secondary Endpoints:
- Impact of applied treatment on primary endpoints: biologics vs conventional treatment
- Impact of potential risk factors on primary endpoints
- Proportion of treatment response and duration of response based on IGA changes
- Disease modification measured as complete remission and number of flares since latest consultation on hands and feet, respectively, HECSI, FE severity, EASI, IGA, RECAP, POEM, DLQI, PGA, WPAI, pruritus NRS, pain NRS, sleep disturbance NRS, depression CES-D

Data analysis plan
Data analysis is descriptive and explorative. Because ReaCT aH&FE is a non-interventional study (observational study), no confirmatory statistical analysis is carried out.

Data management

ENGAGE Goal

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.

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