Prospective, multi-centre, non-interventional safety study to collect real-world data on the safety of immunotherapy with Depigoid® Katze in patients with allergic rhinitis/rhino-conjunctivitis with or without controlled asthma due to feline epithelia (LETI MIAU-KAT 2022)

First published: 04/03/2022

Last updated: 22/05/2025

Study Finalised

Administrative details

EU PAS number

EUPAS46091

Study ID

50362

DARWIN EU® study

No

Study countries

☐ Germany

Study description

Prospective, multi-center, non-interventional safety study collecting real-world data on the safety of immunotherapy with Depigoid® Katze in patients with allergic rhinitis/rhino-conjunctivitis with or without controlled asthma due to feline epithelia.

The total study duration is about 1.5 years.

The duration of the observation of individual patients is 2-3 months. Depending on the dosing regimen, 3 or 5 visits per patient are scheduled.

Approx. 80 centers in Germany with approx. 300 adults and 100 adolescent patients aged ≥ 12 years suffering from persistent moderate to severe allergic rhinitis and/or rhino-conjunctivitis with or without controlled asthma caused by clinically relevant sensitization to cats, demonstrated by a positive skin prick test (wheal diameter ≥ 3 mm) for Felix domesticus animal epithelia.

The decision on the administration of a subcutaneous immunotherapy with Depigoid® Katze had been made based on patients’ symptoms/history prior to study inclusion.

The patients have understood and signed the patient information and declaration of consent. Concomitant asthma must be controlled and stable in accordance with the SmPC. Patients are recruited from the patient pool of the participating centers.

Primary variables and targets:

- Number and severity of systemic reactions (WAO criteria)
- Number and severity of local reactions
- Onset of systemic and/or local reaction (immediate or late phase)

Secondary variables and targets:

-Comparison of two up-dosing regimens (Conventional vs. Quick up-dosing) with regard to the primary variables

-Comparison of two up-dosing regimens in terms of the proportion of patients reaching the maintenance treatment phase
-Comparison of two up-dosing regimens with regard to the proportion of patients with local or systemic reactions
-Development of the quality of life determined with the SF-12 questionnaire

Study status

Finalised

Research institutions and networks

Institutions

ClinCompetence Cologne

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Ralph Mösges

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 23/06/2021

Actual: 23/06/2022

Study start date
Planned: 14/02/2022

Actual: 03/05/2022

Date of final study report
Planned: 01/04/2025

Actual: 31/03/2025

Sources of funding

- Other

More details on funding

LETI Pharma GmbH

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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

Depigoid® Katze is on the German market since 2022 and is used for the treatment of allergic illnesses triggered by feline epithelia.
The objective of the present study is to collect and evaluate real world safety data in patients receiving the SCIT for moderate to severe allergic rhinitis and/or rh.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Post-Authorization Safety Study

Study drug and medical condition

Medical condition to be studied

Rhinitis

Additional medical condition(s)

allergic rhinitis/rhino-conjunctivitis due to feline epithelia

Population studied

Age groups

- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

400

Study design details

Outcomes

• Number and severity of systemic reactions (World Allergy Organisation criteria)
• Number and severity of local reactions
• Onset of systemic and/or local reaction (immediate or late phase),
• Comparison of two up-dosing regimens (Conventional vs Quick) with regard to primary variables
• Comparison of two up-dosing regimens in terms of the proportion of patients reaching the maintenance treatment phase
• Comparison of two up-dosing regimens with regard to the proportion of patients with local or systemic reactions
• Development of the quality of life determined by SF-12 question

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Data analysis plan

Safety and clinical tolerability of the observed medication will be analyzed by the following parameters:
• Number and severity of systemic reactions (World Allergy Organization criteria) in the entire study population (adolescents and adults)
• Number and severity of local reactions in the entire study population (adolescents and adults)
• Onset of systemic and/or local reaction (immediate or late phase) in the entire study population (adolescents and adults)

Summary results

The study was started immediately after the market launch of the product in Germany and encountered a difficult medical-economic environment in which the reimbursement of the therapy was questioned.
It is therefore not surprising that the recruitment period had to be extended and only around a quarter of the originally planned 400 patients were included.
91 patients were treated with the study medication, including 59 men and 32

women. 3 patients prematurely discontinued the study, they were dropped-out after V1 (1 patient), during V2 (1 patient) and after V4 (1 patient). 4 patients were screening failures before receiving the treatment. 88 patients completed the entire treatment course.
Underage patients were also included in the study, so that nine adolescents between the ages of 13 and 16 took part in the study, together with 82 adult patients. Their ages ranged from 18 to 67 years. Regardless of the age group, around 50% of patients mainly reported delayed local side effects.
Nevertheless, all but one patients reached the full maintenance dose and 88 out of 91 treated patients concluded the study. This is in clear contrast to other studies (Jutel, 2024) reporting drop-out rates of 20% or more. The number of systemic side effects documented – limited to grades 1 and 2 only - is comparatively low, mainly affected adults and in majority were delayed supporting the safety profile of Depigoid® Katze.
In this study, in almost 100 patients no emergency hospitalisation or use of adrenaline were reported and confirms a significantly better safety profile than with native allergens for subcutaneous application (Lilja, 1989).
To summarise, Depigoid® Katze – a chemically modified allergoid – provides a well-tolerated and safe immunotherapy option for patients with cat allergies in Germany.
The observations made here largely correspond to those found in a recently published real world study in Spain (de La Torrea, 2024).

Documents

Study results

1.3 List of Data tables.pdf (377.29 KB)

Study report

LETI MIAU-KAT_CSR_20250331_redacted.pdf (1.66 MB)

LETI MIAU-KAT_CSR_final_20250508_redacted.pdf (5.75 MB)

Study, other information

1.1 List of AE-Symptoms.pdf (227.56 KB)

1.2 List of participating investigators.pdf (53.46 KB)

1.4 Federal state specific ICF versions.pdf (89.97 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

Prospective patient-based data collection, Electronic documentation forms for the investigators, Electronic patient diary to determine adverse events and side effects up to the 2nd day after injection, SF12 questionnaires (paper)

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