Incidence of selected adverse events in a population-based Danish cohort with atopic dermatitis treated with conventional systemic therapies: a matched case-cohort study.

First published: 10/11/2025

Last updated: 16/03/2026

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000628

Study ID

1000000628

DARWIN EU® study

No

Study countries

Denmark

Study description

To investigate adverse events of special interest in a dermatologist-verified adult patient population with atopic dermatitis (AD) receiving conventional systemic therapies.

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Simon Francis Thomsen

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 20/02/2025

Actual: 20/02/2025

Study start date
Planned: 07/11/2025

Actual: 07/11/2025

Date of final study report
Planned: 31/12/2025

Study protocol

B3211007_NIS Protocol_AD conventional safety_04Nov2025.pdf (826.38 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:

Secondary use of data

Study design:

This is a retrospective observational cohort register study

Main study objective:

PRIMARY OBJECTIVE:

The primary objective is to quantify the incident rate of major adverse cardiovascular events (MACE) and malignancy (excluding non-melanoma skin cancer (NMSC)) per individual conventional systemic treatment in a dermatologist-verified adult atopic dermatitis (AD) patient population.

SECONDARY OBJECTIVE:

The secondary objective is to quantify the incident rates of additional adverse events of special interest (All-cause mortality, Arterial thromboembolisms, Venous thromboembolisms, Dyslipidemia, Herpes zoster, NMSC, Serious infections,) per individual conventional systemic treatment in a dermatologist-verified adult atopic dermatitis (AD) patient population.

TERTIARY OBJECTIVE:

The tertiary objective is to compare the above identified incident rates of adverse events per individual conventional systemic treatment in a dermatologist-verified adult atopic dermatitis (AD) patient population with the following two matched cohorts: The Danish background population AND Patients diagnosed with AD not receiving systemic therapies (see section 9.7).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

METHOTREXATE (L01BA01 / L04AX03)

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

METHOTREXATE

Anatomical Therapeutic Chemical (ATC) code

(L01BA01) methotrexate

methotrexate

(L04AX03) methotrexate

methotrexate

Population studied

Short description of the study population

Patients with atopic dermatitis (AD) verified by a dermatologist and a background population

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.

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