Pregnancy and Infant Outcomes in Patients Exposed to Nemolizumab During Pregnancy: A Retrospective Observational Study Based on Healthcare Databases (RD.06.SPR.207424)

First published: 06/03/2026

Last updated: 06/03/2026

Study Planned

Administrative details

EU PAS number

EUPAS1000000945

Study ID

1000000945

DARWIN EU® study

No

Study countries

☐ United States

Study description

This will be an observational cohort study that will use multiple existing databases to assess pregnancy and infant outcomes among patients with moderate to severe AD or PN. This study will assess pregnancy and infant outcomes among pregnancies from patients within 3 cohorts:
(1) Nemolizumab Cohort: pregnancies among patients with moderate to severe AD or PN exposed to nemolizumab during pregnancy;
(2) Other AD/PN Treatment Cohort: pregnancies among patients with moderate to severe AD or PN exposed to other AD or PN treatments, including monoclonal antibodies other than nemolizumab, during pregnancy; and
(3) Unexposed Cohort: pregnancies among patients with moderate to severe AD or PN who are not exposed to nemolizumab or any of the comparator AD or PN treatments during pregnancy.

Study status

Planned

Research institutions and networks

Institutions

Optum

☐ Germany

First published: 03/01/2012

Last updated: 07/02/2014

Institution | Outdated | Other | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Andrea CHOMISTEK

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 10/03/2025

Study start date

Planned: 08/12/2032

Date of final study report

Planned: 03/05/2034

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Galderma

Study protocol

riskmgtsystem-pass-protocol.pdf (8.26 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Other study registration identification numbers and links

RD.06.SPR.207424

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This will be an observational cohort study that will use multiple existing databases to assess pregnancy and infant outcomes among patients with moderate to severe AD or PN.

Main study objective:

A) To estimate the frequency of select adverse pregnancy and birth outcomes (i.e., ectopic pregnancy, elective termination, live birth, preterm birth, spontaneous abortion, and foetal death/stillbirth) among pregnant patients with moderate to severe AD or PN who are (1) exposed to nemolizumab, (2) exposed to other treatments for moderate to severe AD or PN, and (3) unexposed.
B) To estimate the frequency of select adverse foetal, neonatal, and infant outcomes (i.e., major congenital malformations [MCMs] and small for gestational age [SGA] birth) among infants from pregnancies in patients with moderate to severe AD or PN who are (1) exposed to nemolizumab, (2) exposed to other treatments for moderate to severe AD or PN, and (3) unexposed.
C) To estimate the adjusted relative risks (RRs) and hazard ratios (HRs) for the study outcomes in pregnant patients in the nemolizumab cohort versus the 2 comparator cohorts.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

NEMLUVIO

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

NEMOLIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(D11AH12) nemolizumab

nemolizumab

Additional medical condition(s)

Atopic Dermatitis, Prurigo Nodularis

Population studied

Short description of the study population

• In utero
• Preterm newborn infants (0 – 27 days)
• Term newborn infants (0 – 27 days)
• Infants and toddlers (28 days – 23 months)
• Adults (18 to < 65 years)

Age groups

- **In utero**
- Neonate
  - Preterm newborn infants (0 – 27 days)
  - Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Adults (18 to < 65 years)
  - Adults (18 to < 46 years)
  - Adults (46 to < 65 years)

Special population of interest

Pregnant women

Study design details

Setting

The source population for this study will include pregnancies that begin (based on ECD) between 12 August 2024 and 31 March 2032 (or most recent data available at the time of the last data extract).

Outcomes

During eligible follow-up, occurrence of pregnancy and infant outcomes will be identified through the presence of corresponding codes in the database. Published, validated algorithms will be used when available. The pregnancy outcomes will include ectopic pregnancy, elective termination, live birth, preterm birth, spontaneous abortion, and stillbirth, while infant outcomes are MCMs (primary outcome) and SGA birth. Code lists for all outcomes can be found in Appendix E.

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 source(s), other

Optum Research Database

Data sources (types)

Administrative healthcare records (e.g., claims)

Non-interventional study

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes

Data characterisation moment

after data extraction

after extract-transform-load to a common data model

after creation of study variables