# Post-authorisation Safety Study of Tralokinumab Use in Pregnancy: An Observational Study Based on Electronic Healthcare Data

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Study | Planned

## Administrative details

### Contact details

**Study institution contact**
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Study contact

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**Primary lead investigator**
Elena Rivero
Primary lead investigator

**PURI**
https://redirect.ema.europa.eu/resource/104924

**EU PAS number**
EUPAS104085

**Study ID**
104924

**DARWIN EU® study**
No

**Study countries**
France
Germany
United States

**Study description**
This study will investigate whether maternal exposure to tralokinumab during pregnancy is associated with increased risk of adverse pregnancy and infant outcomes: major congenital malformations, infants born small for gestational age, preterm births, spontaneous abortions, or stillbirths. This is an observational cohort study using prospectively collected secondary health care data from 1 US and 2 European data sources. Three study groups will be included: 1) a tralokinumab-exposed group of pregnant women with atopic dermatitis (AD) treated with tralokinumab, 2) a primary comparator group of pregnant women with AD exposed to other, non-tralokinumab, systemic treatments for AD, and 3) a secondary comparator group of pregnant women with AD unexposed to tralokinumab or other systemic therapies for AD.

**Study status**
Planned

# Research institution and networks

## Institutions

### RTI Health Solutions (RTI-HS)
France
Spain
Sweden
United Kingdom
United Kingdom (Northern Ireland)
United States
**First published:** 21/04/2010
Last updated 19/02/2024

Institution
ENCePP partner
Not-for-profit

## Leibniz Institute for Prevention Research and Epidemiology - BIPS

Germany
**First published:** 29/03/2010
Last updated
26/02/2024

Institution | Not-for-profit | ENCePP partner

## Bordeaux PharmacoEpi, University of Bordeaux

France
**First published:** 07/02/2023
Last updated
08/02/2023

Institution | Educational Institution | Hospital/Clinic/Other health care facility | Not-for-profit | ENCePP partner

## Carelon Research Delaware, United States

# Study timelines

**Date when funding contract was signed**
Planned:
01/07/2021
Actual:
27/07/2021

**Data collection**
Planned:
01/10/2026

**Start date of data analysis**
Planned:
08/01/2027

**Date of interim report, if expected**
Planned:
30/06/2027

**Date of final study report**
Planned:
31/12/2030

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Leo Pharma A/S

## 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)

# Methodological aspects

## Study type

## Study type list

**Study type:**
Non-interventional study

**Scope of the study:**
Assessment of risk minimisation measure implementation or effectiveness
Drug utilisation

**Main study objective:**
The study will investigate whether maternal exposure to tralokinumab during pregnancy in women with AD is associated with an increased risk of major congenital malformations, minor congenital malformations, infants born small for gestational age, preterm births, spontaneous abortions, or stillbirths

## Study Design

**Non-interventional study design**
Cohort

## Study drug and medical condition

**Name of medicine**
Adtralza

**Name of medicine, other**
Adbry

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

**Anatomical Therapeutic Chemical (ATC) code**
200000016031
tralokinumab

**Medical condition to be studied**
Dermatitis atopic

## Population studied

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

**Special population of interest**
Pregnant women

**Estimated number of subjects**
11880

# Study design details

**Outcomes**
Major congenital malformations, Minor congenital malformations, infants born small for gestational age, preterm births, spontaneous abortions, stillbirths

**Data analysis plan**
Descriptive analyses will be conducted for the progress reports to monitor counts of tralokinumab-exposed pregnancies and live births. The following analyses will be conducted for the final study report: • Descriptive analyses of demographic and baseline characteristics and the number of dispensations of the exposure medications will be conducted for each cohort and will include counts, frequency, mean and 95% CI, median, Q1 and Q3, minimum, and maximum. Results will be presented by data source. • Comparative analyses, including crude and adjusted RRs and risk differences and 95% CIs will be calculated for all pregnancy and infant outcomes by data source. • For each study outcome, the effect estimates from each data source will be pooled using meta-analytic techniques.

# Data management

# ENCePP Seal

**This study has been awarded the ENCePP seal**


**Conflicts of interest of investigators**
Annex5_DoIForm_Rivero.pdf(903.69 KB)
DOIForms_All.pdf(7.7 MB)

**Composition of steering group and observers**
EUPAS104085_No steering group.pdf(68.37 KB)

## Data sources

**Data source(s)**
German Pharmacoepidemiological Research Database

**Data source(s), other**
Système National des Données de Santé (SNDS) France, Healthcare Integrated Research Database (HIRD) United States

**Data sources (types)**
Administrative data (e.g. claims)
Drug dispensing/prescription data

# 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