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

First published: 18/04/2023

Last updated: 20/09/2024

Study Planned

Administrative details

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 institutions 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: 13/03/2025

Institution | Not-for-profit | ENCePP partner

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

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Elena Rivero

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/07/2021

Actual: 27/07/2021

Study start date

Planned: 01/10/2026

Data analysis start date

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:

Drug utilisation

Safety study (incl. comparative)

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 relative to non-exposure to tralokinumab during pregnancy.

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

(D11AH07) tralokinumab

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

Primary outcomes: Major congenital malformations

Secondary outcomes: Minor congenital malformations, infants born small for gestational age, preterm births, spontaneous abortions, stillbirths

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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 update_September 2024.pdf(6.46 MB)

Composition of steering group and observers

EUPAS104085_No steering group.pdf(68.37 KB)

Signed code of conduct

Annex3_Declaration_Rivero.pdf(129.75 KB)

Signed code of conduct checklist

Annex2_Checklist_Rivero.pdf(116.57 KB)

Signed checklist for study protocols

NIS-tralo-2178 protocol 2.0 final_ENCePP Checklist_Redacted.pdf(773.23 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 healthcare records (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