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

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Administrative details

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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

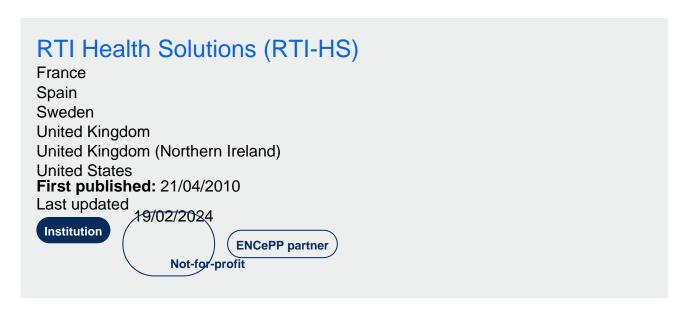
This study will investigate whether maternal exposure to tralokinumab during pregnancy is associated with increased risk of adverse pregnancy and infant outcomes: major congenital malformations, infants born small for gestational age, preterm births, spontaneous abortions, or stillbirths. This is an 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



Leibniz Institute for Prevention Research and Epidemiology - BIPS Germany First published: 29/03/2010 Last updated 26/02/2024 Institution ENCePP partner Not-for-profit



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 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

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_DolForm_Rivero.pdf(903.69 KB) DOlForms_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