A Non-interventional Multi-country Cohort Study to Assess the Safety of EVUSHELD™ (Tixagevimab/Cilgavimab) During Pregnancy (O-STEREO Study)

First published: 05/12/2022

Last updated: 04/12/2025

Study | Discontinued

Administrative details

EU PAS number

EUPAS49565

Study ID

49566

DARWIN EU® study

No

Study countries

Canada

France

United States

Study description

To characterise the risk of pregnancy and offspring (neonatal and infant) outcomes in pregnancies with and without exposure to EVUSHELD among women of child-bearing indicated for such treatment in the real-world setting. This non-interventional multi-country cohort study or post-authorisation safety study (PASS) in pregnancy has been designed to fulfil EVUSHELD's pharmacovigilance plan as specified in the EVUSHELD Core Risk Management Plan (RMP), and notably in the additional pharmacovigilance activities in the EVUSHELD EU RMP.

Study status

Discontinued

Research institutions and networks

Institutions

Aetion

Spain

First published: 24/11/2022

Last updated: 16/07/2024

Institution **Other** **ENCePP partner**

Bordeaux PharmacoEpi, University of Bordeaux

France

First published: 07/02/2023

Last updated: 08/12/2025

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

CaMCCo listed on Bridge-to-Data platform and the Maestrom Research Databases platform Canada

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Lecomte Coralie

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 27/06/2022

Actual: 27/06/2022

Study start date
Planned: 01/04/2023

Date of final study report
Planned: 31/12/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

Study protocol

D8850R00006 CSP v1.0_redacted.pdf (7.55 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)

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:

To characterise the risk of pregnancy and offspring (neonatal and infant) outcomes in pregnancies with and without exposure to EVUSHELD among women of child-bearing indicated for such treatment in the real-world setting.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

CILGAVIMAB

TIXAGEVIMAB

Medical condition to be studied

Pregnancy

Exposure during pregnancy

Stillbirth

Abortion spontaneous

Ectopic pregnancy

Gestational hypertension

Gestational diabetes

Congenital anomaly

Foetal growth restriction

Failure to thrive

Death neonatal

Neonatal respiratory distress syndrome

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

Immunocompromised

Pregnant women

Estimated number of subjects

0

Study design details

Outcomes

1. Describe the risk of pregnancy outcomes in EVUSHELD-exposed pregnancies and, for contextualisation purposes only, in matched unexposed pregnancies. 2. Describe the risk of offspring outcomes in EVUSHELD-exposed pregnancies and, for contextualisation purposes only, in matched unexposed pregnancies. 1. Describe EVUSHELD utilisation patterns, including number of doses, cumulative dose, and duration of treatment, among EVUSHELD-exposed pregnancies. 2. Describe the risk of the pregnancy and offspring outcomes among EVUSHELD-exposed pregnancies within strata of individual and pregnancy characteristics: maternal age, high-risk condition type, trimester of index date, recent SARS-COV-2 infection

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Data analysis plan

Primary analyses: For each analytic cohort, a descriptive analysis of baseline characteristics, pregnancy characteristics, pregnancy history, laboratory tests, comorbidities, co-medications and substance abuse, and offspring characteristics will be conducted stratified by EVUSHELD exposure. The risk with associated 95% confidence interval of each outcome will be reported in pregnancies with EVUSHELD exposure and pregnancies without EVUSHELD exposure. Secondary analyses: The EVUSHELD exposure characteristics will be summarised descriptively in the exposure group. In addition, pregnancy and offspring outcomes will be described among EVUSHELD-exposed pregnancies within strata of pregnancy characteristics. Comparative exploratory analysis: PS matching will be used to control confounding. Modified Poisson regression models will be used to estimate risk ratios. Risk differences will be estimated by Poisson regression using an identity link with robust standard errors.

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

HealthVerity Maternal Outcomes Masterset United States, SNDS (Système National des Données de Santé) France, CaMCCo (Canadian Mother-Child Cohort) Canada

Data sources (types)

Administrative healthcare records (e.g., claims)

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