A Non-Interventional Multi-Database Post-Authorisation Study to Assess Pregnancy-Related Safety Data from Women with Severe Asthma Exposed to Tezepelumab (TREATY)

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000176

EU PAS number

EUPAS1000000176

Study ID

1000000176

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] France
- [ ] Sweden
- [ ] United States

Study description

This study is an observational cohort study utilising secondary data from multiple data sources from Denmark, France, Sweden, and the United States of America (USA). The study will describe and compare the following outcomes in pregnancies and offspring from women with severe asthma exposed to tezepelumab and women with severe asthma unexposed to tezepelumab, treated with SOC for severe asthma (with or without other biologics) during pregnancy: MCM and mCM, foetal death (composite of miscarriage, stillbirth, and ectopic pregnancy), individual adverse pregnancy outcomes (ectopic pregnancy, miscarriage, stillbirth, TOP, and pre-eclampsia), and individual adverse birth outcomes (EC-section, PTB, SGA, and LBW). The unit of analysis is individual pregnancies in women with severe asthma (i.e., each woman may contribute multiple pregnancies to the study).

Study status

Planned

Research institutions and networks

Institutions

Global Database Studies, IQVIA

- [ ] Czechia

☐ Finland

☐ Germany

☐ Slovakia

☐ Spain

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Institution | Other | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Peter Egger

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 19/12/2022

Actual: 28/02/2023

Study start date

Planned: 30/06/2027

Data analysis start date
Planned: 30/06/2027

Date of interim report, if expected
Planned: 30/03/2028

Date of final study report
Planned: 31/03/2034

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

ASTRAZENECA PHARMACEUTICALS LP

Study protocol

D5180R00010 PASS Protocol v3.0_Redacted.pdf(2.29 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 topic:

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:

The study will apply a non-interventional, longitudinal, population-based, cohort design using multiple secondary data sources. The study will describe and compare outcomes in pregnancies and offspring of women with severe asthma treated with SOC with vs without exposure to tezepelumab in pregnancy.

Main study objective:

To estimate the risk and relative risk of major congenital malformations in live and non-live offspring, and termination of pregnancy for foetal anomaly (TOPFA) among women with severe asthma treated with SOC with vs without exposure to tezepelumab during first trimester of pregnancy.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

TEZSPIRE 210 MG - SOLUTION FOR INJECTION

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

TEZEPELUMAB

Anatomical Therapeutic Chemical (ATC) code

(R03DX11) tezepelumab

tezepelumab

Medical condition to be studied

Asthma

Additional medical condition(s)

Severe Asthma

Population studied

Short description of the study population

The source population comprises of women with asthma and at least one pregnancy record during the study period. Pregnancies are identified using maternal medical records related to pregnancy, including pregnancy loss, antenatal visits, deliveries and other EoP events. Inclusion and exclusion criteria will be applied to each pregnancy to create the study population consisting of pregnancies in women with severe asthma during pregnancy, from which the exposed and unexposed cohorts will be identified.

Inclusion criteria: 1) start of pregnancy available as recorded or calculated based on gestational age information at pregnancy record, 2) continuous

database enrollment at least 12 months prior to pregnancy, 3) severe asthma overlapping with pregnancy (based on treatment algorithm for asthma severity as specified in GINA guidelines)

Exclusion criteria: 1) pregnancies following IVF treatment, 2) multiples, 3) foetal chromosomal abnormalities, pregnancies with exposure to other known teratogens, 4) maternal MCM diagnosed prior to current pregnancy and not in relation to previous pregnancies.

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 < 46 years)

Special population of interest

Pregnant women

Estimated number of subjects

441

Study design details

Setting

A total of four large longitudinal patient-level data sources have been selected for this study, representing four countries: Denmark, France, Sweden, and USA.

The included data sources are:

1. Danish National Health and Socioeconomic Registries (Denmark)
2. French National Health Data System (SNDS) (France)
3. Swedish National Health Registries (Sweden)
4. Carelon (USA)

Comparators

Pregnancy and infant outcomes in pregnancies among women exposed to tezepelumab in addition to standard of care (SOC) will be compared to women exposed to SOC but unexposed to tezepelumab during pregnancy. A sensitivity analysis will compare to SOC excluding all other biologics.

Outcomes

Major and minor congenital malformations, foetal death (individual and composite of miscarriage, stillbirth and ectopic pregnancy), termination of pregnancy, pre-eclampsia, emergency c-section, preterm birth, small for gestational age, low birth weight.

Data analysis plan

A full description of the analytical approach will be developed and described in the SAP. Details on data derivations, category definitions, analyses, handling of missing data, and presentation of the study results will be provided in SAP. SAP will be finalised prior to the conduct of the study analyses. All study results will be presented separately for each country in the study reports, as appropriate when data become available. The final study report will include all descriptive, comparative, exploratory and sensitivity analyses as well as the meta-analysis for all the data sources.

Data management

Data sources

Data source(s)

Système National des Données de Santé (French national health system main database)

Data source(s), other

Denmark (National Registries/National Health and Socioeconomic Registries), Sweden (National Registers), and United States (Carelon).

Data sources (types)

Non-interventional study

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

ConcepTION CDM

CDM website

https://www.imi-conception.eu/

CDM release frequency

6 months

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No