Pregnancy Surveillance Program of Women and Infants Exposed to TEGSEDI During Pregnancy (TEG4005)

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Study Planned

Administrative details

EU PAS number

EUPAS41839

Study ID

41840

DARWIN EU® study

No

Study countries

- Bulgaria
- Canada
- Cyprus
- France

Germany
Greece
Italy
Portugal
Spain

Study description

This is a worldwide observational pregnancy surveillance program (PSP) of pregnancy exposures to TEGSEDI.

The study is designed to estimate the frequency of selected pregnancy, fetal/neonatal and pregnancy complications outcomes from the TEGSEDI exposed and unexposed patients.

Pregnancies will be reported voluntarily to the centrally located Pregnancy Call Center (PCC) by Healthcare Providers (HCPs), by patients and by secondary contacts.

Patients will be identified from the online website, from any ongoing clinical trials, post market studies, pharmacovigilance cases or the TEGSEDI Risk Evaluation and Mitigation Strategy (REMS) Program.

Study status

Planned

Research institutions and networks

Institutions

Akcea Therapeutics, Inc.

Contact details

Study institution contact

Akcea Therapeutics, Inc. globalregulatoryaffairs@ionis.com

Study contact

globalregulatoryaffairs@ionis.com

Primary lead investigator

Akcea Therapeutics, Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 19/10/2019

Actual: 04/02/2020

Study start date

Planned: 31/12/2025

Date of final study report

Planned: 31/12/2031

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Akcea Therapeutics, Inc.

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:

Other

If ‘other’, further details on the scope of the study

Pregnancy Surveillance Program

Study design:

This is a worldwide observational pregnancy surveillance program (PSP) of pregnancy exposures to TEGSEDI. The study is designed to estimate the

frequency of selected pregnancy, fetal/neonatal and pregnancy complications outcomes from the TEGSEDI exposed and unexposed patients.

Main study objective:
The objectives of this PSP are to:
• Estimate the frequency of selected pregnancy and fetal/neonatal outcomes through 1 year of age in women who were exposed to at least 1 dose of TEGSEDI (Cohort 1) within 25 weeks prior to conception or during pregnancy, with the exposure window of interest for major congenital malformations being the first trimester, and in the unexposed cohort of pregnant women (Cohort 2) who have a diagnosis of hATTRPN
- pregnancy outcomes include live births, spontaneous abortions, stillbirths, elective abortions, preterm birth
- fetal/neonatal outcomes include major and minor congenital malformations, small for gestational age, failure to thrive, and postnatal development
• Estimate the frequency of selected pregnancy complications in women who were exposed to TEGSEDI (Cohort 1) within 25 weeks prior to conception or during pregnancy and in the unexposed cohort of pregnant women (Cohort 2) who have a diagnosis of hATTR-PN

Study Design

Non-interventional study design
Cohort
Other

Non-interventional study design, other
Pregnancy surveillance program

Study drug and medical condition

Medicinal product name

TEGSEDI

Additional medical condition(s)

Pregnancy Hereditary Transthyretin Amyloidosis with Polyneuropathy (hATTR-PN)

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

20

Study design details

Setting

The study will actively pursue and attempt to capture all pregnancies that meet the eligibility criteria that occur worldwide.

Outcomes

Primary Outcome Measures:

1. Frequency of Selected Pregnancy and Fetal/Neonatal Outcomes

Estimate the frequency of selected pregnancy and fetal/neonatal outcomes through 1 year of age in women who were exposed to at least 1 dose of TEGSEDI (Cohort 1) within 25 weeks prior to conception or during pregnancy, with the exposure window of interest for major congenital malformations being the first trimester, and in the unexposed cohort of pregnant women (Cohort 2) who have a diagnosis of hereditary transthyretin amyloidosis with polyneuropathy (hATTR-PN)

• pregnancy outcomes include live births, spontaneous abortions, stillbirths, elective abortions, preterm birth

• fetal/neonatal outcomes include major and minor congenital malformations, small for gestational age, failure to thrive, and postnatal development

[Time Frame: 10 years or 12 months after the last live birth whichever is later]

2. Frequency of Selected Pregnancy Complications

Estimate the frequency of selected pregnancy complications in women who were exposed to TEGSEDI (Cohort 1) within 25 weeks prior to conception or during pregnancy and in the unexposed cohort of pregnant women (Cohort 2) who have a diagnosis of hATTR-PN

[Time Frame: 10 years or 12 months after the last live birth whichever is later]

Data analysis plan

The primary outcomes of interest are major congenital malformations (MCMs) as reviewed and classified using both the conventions of the Metropolitan Atlanta Congenital Defects Program (MACDP) (Correa, 2007) and European Registration of Congenital Anomalies and Twins (EUROCAT) definitions.

For these outcomes, the prevalence will be summarized using all live births as the denominator in computing the rates. A 2-sided 95% confidence interval for these rates will be calculated using exact (Clopper-Pearson) methods. Analysis

will be repeated by trimester of first exposure and by the timing of exposure beginning prior to or during pregnancy, with the exposure window of interest for MCMs being the first trimester.

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 sources (types)

Other

Data sources (types), other

both retrospective and prospective cases will be collected

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