Monitoring of pregnancy outcomes in women treated with inclisiran: a non-interventional study

First published: 07/10/2021

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Study Ongoing

Administrative details

EU PAS number

EUPAS42905

Study ID

50706

DARWIN EU® study

No

Study countries

Switzerland

Study description

This post-authorisation safety study is a worldwide, single-arm descriptive non-interventional study that collects prospective and retrospective data in women exposed to inclisiran during pregnancy. It uses an enhanced pharmacovigilance data collection and processing system via a set of targeted checklists, structured follow-up, rigorous process of data entry and data quality control, and programmed aggregate analysis. The overall objective of the study is to collect data on pregnancy outcomes in patients treated with inclisiran during or prior to pregnancy. Although pharmacovigilance data may be collected from any country in the world where the product is approved, the anonymized patient level data will be analyzed at a global level in Switzerland.

Study status

Ongoing

Research institutions and networks

Institutions

Novartis Pharmaceuticals

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Novartis Clinical Disclosure Officer

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 09/12/2020

Actual: 09/12/2020

Study start date
Planned: 31/12/2021

Actual: 31/12/2021

Data analysis start date
Planned: 31/01/2031

Date of final study report
Planned: 31/07/2031

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis Pharma AG

Study protocol

CKJX839A12011-v00--protocol_Redacted.pdf (726.72 KB)

CKJX839A12011_Protocol V2_Redacted.pdf (593.52 KB)

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)

Other study registration identification numbers and links

CKJX839A12011

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Main study objective:

To estimate the proportion of major congenital malformations among pregnancies exposed to inclisiran during pregnancy prospectively reported to Novartis amongst (i) live births and (ii) live births plus still births plus termination of pregnancy for fetal anomaly (TOPFA).

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Intensive monitoring schemes

Study drug and medical condition

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

INCLISIRAN

Anatomical Therapeutic Chemical (ATC) code

(C10AX16) inclisiran

inclisiran

Population studied

Age groups

- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

500

Study design details

Outcomes

Major congenital malformations (MCM) among pregnancies exposed to inclisiran during pregnancy, • To estimate the proportion of MCM among pregnancies exposed to inclisiran prior to the last menstrual period (LMP) • To compare the frequency of MCM among pregnancies exposed to inclisiran with the background frequencies • To estimate the proportion of other secondary outcomes in pregnancies exposed to inclisiran prior to LMP and during pregnancy

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Data analysis plan

Data analysis will focus on the prospectively reported pregnancy cases. Retrospective pregnancy cases will also be analyzed and presented separately from the prospective cases. Data analysis will include the estimation of proportion (and 95% confidence interval) of malformations (major, minor, and overall), and of specific pregnancy outcomes such as live births, stillbirths, spontaneous abortions and elective terminations. Proportions will be estimated

by timing of drug exposure in pregnancy (during pregnancy and prior to LMP, as well as by trimester if sample size allows). Descriptive analysis will be performed for all prospective pregnancy cases including case disposition (outcome known, pending, and lost to follow-up) and maternal characteristics (i.e. age, ethnicity, region) by providing the number and percentage of pregnancies in each category. Further stratified analyses may be undertaken if sample size allows.

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

Spontaneous reports of suspected adverse drug reactions

Data sources (types), other

targeted follow-up questionnaires for reported pregnancy cases

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

Not applicable