

NN9536-4937 Wegovy® (semaglutide 2.4 mg) Pregnancy Registry Study: A Prospective Cohort Study to Investigate Safety Outcomes of Exposure to Wegovy during Pregnancy

First published: 10/05/2023

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Study

Ongoing

Administrative details

EU PAS number

EUPAS104613

Study ID

105697

DARWIN EU® study

No

Study countries

 Spain

 United Kingdom

Study description

This is an observational, prospective Wegovy (semaglutide 2.4 milligram mg) Pregnancy Registry Study. The aim of this study is to compare the maternal, foetal, and infant outcomes of pregnant women who are exposed to Wegovy during pregnancy for the treatment of obesity or overweight with at least one weight-related comorbid condition with outcomes in an internal comparison cohort of pregnant women with obesity or overweight with at least one weight related comorbid condition at conception and who are not exposed to Wegovy or other glucagon-like peptide-1 receptor agonists (GLP-1 RAs) during pregnancy. Infant outcomes will be assessed throughout the infant's first year of life, with active data collection by the registry occurring at 4 and 12 months after delivery.

Study status

Ongoing

Research institutions and networks

Institutions

[Novo Nordisk](#)

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Institution

Contact details

Study institution contact

Clinical Reporting Novo Nordisk
clinicaltrials@novonordisk.com

Study contact

clinicaltrials@novonordisk.com

Primary lead investigator

Clinical Transparency (dept.2834) Novo Nordisk A/S

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 05/01/2023

Study start date

Planned: 01/06/2023

Actual: 19/06/2023

Date of final study report

Planned: 30/11/2033

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novo Nordisk A/S

Study protocol

[4937 16-1-01 protocol eu-pas-reg redacted.pdf](#) (1.4 MB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Non-EU RMP only

Other study registration identification numbers and links

UTN: U1111-1273-4336

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Main study objective:

The primary objective is to compare the overall prevalence of Major Congenital Malformations (MCM) between cohorts.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

SEMAGLUTIDE

Medical condition to be studied

Obesity

Additional medical condition(s)

pregnant women with overweight or obesity

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

728

Study design details

Outcomes

Number of Infants with Major Congenital Malformation (MCM), Number of Infants with: Minor Congenital Malformation Postnatal Growth Deficiency Developmental Delay Small for Gestational Age (SGA) Birth Number of Pregnant Participants With: Pre-eclampsia Eclampsia Elective Termination Preterm Delivery Number of pregnant Participants Experiencing: Spontaneous Abortion Stillbirth

Data analysis plan

Registry data will be summarised in tables and listings by study cohort, as appropriate. Comparisons of demographic and baseline characteristics and prevalence of the outcomes will be conducted between the study cohorts. In addition, the prevalence of the outcomes in the general population and/or populations of women with overweight or obesity will be used to put the registry-observed outcome prevalences into context.

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

Prospective patient-based data collection

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