# 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

**Last updated:** 14/03/2024

Study Ongoing

## Administrative details

**PURI**

https://redirect.ema.europa.eu/resource/105697

**EU PAS number**

EUPAS104613

**Study ID**

105697

**DARWIN EU® study**

No

**Study countries**

- [ ] Spain
- [ ] United Kingdom
- [ ] United States

**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

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

## Contact details

**Study institution contact**

Clinical Reporting Novo Nordisk

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

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**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

## 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